JOSEPH P. RUSSONIELLO
United States Attorney
CHARLES O'CONNOR
Assistant United States Attorney
450 Golden Gate Ave., Box 36055
San Francisco, CA 94102
Telephone: (415) 536-6967
Facsimile: (415) 436-6748

RONALD J. TENPAS
Assistant Attorney General
BARCLAY T. SAMFORD (NMBN 12323)
Trial Attorney
U.S. Department of Justice
Environment & Natural Resources Div.
1961 Stout St., 8th Floor
Denver, CO 80294
Telephone: (303) 844-1475
Facsimile: (303) 844-1350

Attorneys for Defendants

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

TRI-VALLEY CARES, MARYLIA KELLEY, JANIS KATE TURNER, and JEDIDJAH DE VRIES, Plaintiffs, v. UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION, LAWRENCE LIVERMORE NATIONAL LABORATORY, Defendants.	Case No. 08-cv-1372-SBA DECLARATION OF BARCLAY SAMFORD

I, Barclay Samford, state and declare as follows:

1. I am attorney with the U.S. Department of Justice, Environment and Natural Resources Division, Natural Resources Section. I am counsel for Federal Defendants in the above-captioned case. I make the statements set forth in this declaration on the basis of personal knowledge.

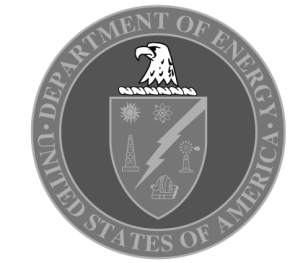
2. To the best of my knowledge, attached to this declaration are true and correct copies of the following documents, which are cited as exhibits in support of Defendants' Memorandum in Opposition to Plaintiffs' Motion for Preliminary Injunction.

Exh. No.	Description
1.	Final Revised Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory Livermore, California, January 2008
2.	Tri-Valley CARES v. U.S. Dep't of Energy, Case No.03-cv-03926-SBA (N.D. Cal. Sept. 10, 2004)
3.	Tri-Valley CARES v. U.S. Dep't of Energy, No 04-17232 (9th Cir. Oct. 16, 2006)
4.	U.S. Department of Energy Revised Finding of No Significant Impact for the Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Jan. 25, 2008
5.	Declaration of Eric Gard
6.	Appendix C: Public Comments on Final Revised Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory Livermore **[Excerpts]**
7.	Declaration of Leslie A. Hofherr
8.	"Recommendations for Analyzing Accidents under the National Environmental Policy Act," U.S. Department of Energy, Office of NEPA Policy and Compliance, July 2002
9.	National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules, April 2002 **[Excerpts]**
10.	Declaration of Jeffrey Stiefel
11.	Declaration of Susan Elizabeth George

/s/ Barclay T. Samford
BARCLAY T. SAMFORD
Counsel for Defendants

EXHIBIT 1

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION



DOE/EA-1442R

Final Revised Environmental Assessment for The Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California

Issued: December 2002

Revised: January 2008

Department of Energy
National Nuclear Security Administration
Livermore Site Office

This page intentionally left blank.

FORWARD

The National Nuclear Security Administration (NNSA) of the Department of Energy (DOE) has responsibility for national programs to reduce and counter threats from weapons of mass destruction including nuclear, chemical, and biological weapons (bioweapons). NNSA's bioscience work at Lawrence Livermore National Laboratory (LLNL) in support of these missions requires work with infectious agents, including those historically used for bioweapons. Much of the proposed work must be performed with Biosafety Level 3 (BSL-3) containment and protection. Accordingly, NNSA proposed to construct and operate a BSL-3 facility at LLNL to meet the NNSA mission to "develop, demonstrate and deliver technologies and systems to improve domestic defense capabilities and, ultimately, to save lives in the event of a chemical or biological attack." A Environmental Assessment (EA) and a Finding of No Significant Impact for the proposed BSL-3 facility was issued in December 2002 (BSL-3 EA, DOE/EA-1442), and construction of the facility began.

On September 16, 2003, Tri-Valley CARES filed a lawsuit in the federal district court in San Francisco challenging the adequacy of the EA for the proposed BSL-3 facility. On September 10, 2004, the district court found the EA to be adequate. On November 8, 2004**,** Tri-Valley CARES filed a notice of appeal with the Ninth Circuit Court of Appeals. On October 16, 2006, the appellate court issued a memorandum opinion (D.C No CV-03-03926-SBA). In light of the Ninth Circuit's recent ruling in an unrelated case, the court remanded the matter for DOE to consider whether the threat of potential terrorist activity necessitates the preparation of an environmental impact statement. DOE issued interim guidance on how to address intentional destructive acts in NEPA documents (DOE 2006) as a result of the Ninth Circuit's decision.

In response to this ruling and the guidance, NNSA has revised the 2002 EA to consider the potential impacts of terrorist activity. NNSA has limited the changes to the document in matters not related to the terrorist analysis; however, some updates were necessary. The Appendices to the original EA were not revised. Since this EA, NNSA has issued the *Final Site-wide Environmental Impact Statement for Continued Operation of Lawrence Livermore National Laboratory and Supplemental Stockpile Stewardship and Management Programmatic Environmental Impact Statement* (SWEIS, DOE/EIS-0348, DOE/EIS-0236-S3, DOE 2005). Background information in this EA has been updated to reflect more current information in the SWEIS if the updated information is pertinent to NNSA's determination of the potential effects of the proposed action on human health or the environment. Also since 2002, the proposed building has been constructed and all facility-related equipment installed. As such, NNSA acknowledges that the impacts related to construction that are discussed in this document have already occurred; these impacts were analyzed in the 2002 EA and considered in issuing the Finding of No Significant Impact (FONSI). Other minor changes have been made if guiding regulations or DOE policies have been updated since 2002. Change bars (a vertical line in the margin next to the text which was changed) indicate significant changes in the document made since the revised draft was made available for public comment in March, 2007.

EXECUTIVE SUMMARY

The National Nuclear Security Administration (NNSA) of the Department of Energy (DOE) has responsibility for national programs to reduce and counter threats from weapons of mass destruction including nuclear, chemical, and biological weapons (bioweapons). NNSA's bioscience work at Lawrence Livermore National Laboratory (LLNL) in support of these missions requires work with infectious agents, including those historically used for bioweapons. The laboratory's pioneering work on biological agent (bioagent) detection and counter-terrorism technologies, and basic research understanding of emerging and re-emerging natural diseases are key elements of the LLNL efforts to support the NNSA mission. As a result, the need to conduct research with infective agents in a secure environment at LLNL and within NNSA is growing rapidly.

DOE does not currently operate any microbiological laboratory facility above Biosafety Level 2 (BSL-2). Much of the proposed work must be performed with Biosafety Level 3 (BSL-3) containment and protection. BSL-3 facilities provide for environmentally safe and physically secure manipulation and storage of infectious microorganisms, many of which are potential bioweapon agents. NNSA's BSL-3 work would require efficient high-quality sample processing, and, for scientific and security reasons, assurance of sample security and integrity. These requirements also necessitate that cross-contamination and degradation of samples be minimized by reducing excessive handling and transportation. Commercial or governmental BSL-3 facilities currently available are often heavily committed to other projects or tailored to work with specific types of microorganisms. In order to more effectively utilize and capitalize on LLNL's existing onsite facilities, expertise, and capabilities, and ensure the necessary quality, integrity, and security of microbiological work, NNSA needs BSL-3 laboratory capability at LLNL.

The Proposed Action and alternatives differ mainly in how the facility would be constructed. In all but the No-Action alternative, the BSL-3 facility would be designed and operated in accordance with guidance for BSL-3 laboratories established by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). Physical security would be implemented commensurate with the level of work being performed within the facility. No radiological, high explosives, or propellant material would be used or stored in the proposed BSL-3 facility. The proposed facility would have the unique capability within DOE to perform aerosol studies to include challenges of rodents using infectious agents or biologically derived toxins (biotoxins). Sample shipments would be received only in compliance with all established shipping guidelines and requirements. The samples would be stored in the BSL-3 laboratory within a locked labeled freezer or refrigerator according to the needs of the sample for preservation. Biological wastes would be disposed of in accordance with CDC and NIH guidance, and other applicable federal, state, and local regulations.

The Proposed Action is to assemble on-site an approximately 1,500 ft^2, one-story permanent prefabricated BSL-3 laboratory facility which would have three individual BSL-3 laboratory rooms (one capable of handling rodents), a mechanical room, clothes-change and shower rooms, and small storage space. The building footprint would take less than one-quarter acre. It is estimated that the operational design life of the proposed building would be at least 30 years.

Under the Remodel/Upgrade Alternative, NNSA would create a single BSL-3 laboratory from an existing BSL-2 laboratory at LLNL. This would require substantial building modification and probable disruption of other on-going work in the facility. This alternative has the lowest waste generation during construction and operation since it is only a single laboratory while the other two options consist of three laboratories each. This alternative would be in accordance with NNSA's purpose and need for action. Being only a single BSL-3 laboratory, it would be self-limiting to the amount of research that could be conducted.

The Construct On-Site Alternative would meet NNSA's purpose and need for action. This alternative does not differ significantly from the Proposed Action for operation and decontamination and decommissioning with one exception. The longer time it takes to construct the facility under this alternative affects the duration of noise, dust, and truck traffic and disruption of workers in adjacent buildings. This longer period also means it would be months longer before the facility would be operational.

Under the No Action Alternative, NNSA would not construct or place a BSL-3 facility at LLNL. In this event, NNSA would continue to have its BSL-3 laboratory needs met by using existing or new BSL-3 laboratories located offsite from LLNL. There would continue to be certain NNSA national security mission needs that could not be met in a timely fashion, or that may not be able to be met at all. The No Action Alternative would not meet the NNSA's identified purpose and need for action.

The environmental consequences from site preparation, construction and routine operation would be minor and would not differ greatly between the Proposed Action and alternatives. The potential human health effects of the proposed BSL-3 laboratory would be the same as those demonstrated for similar CDC-registered laboratories that are required to implement the guidelines established mutually by the CDC and NIH. Relevant human health information gathered from LLNL's past experience with BSL-1 and BSL-2 laboratories, from the U.S. Bureau of Labor Statistics, and from anecdotal information in published reports, indicates that while laboratory-acquired or laboratory-associated infections sometimes occur, they should be considered abnormal events due to their infrequency of occurrence (see Appendix B). As such, the potential human health effects from these events are discussed as Abnormal Events and Accidents. No cases of illness would be expected to result from implementing the Proposed Action as a result of an abnormal event or accident.

On September 16, 2003, suit was filed in federal district court challenging the adequacy of the prior version of this EA. The district court ruled that the EA was adequate and plaintiffs appealed to the Ninth Circuit. In October 2006, the appellate court issued its decision. It concluded that while NNSA did take a hard look at identified environmental concerns and that its decision was fully informed and well-considered, the NNSA had not considered whether the threat of potential terrorist activity would necessitate the preparation of an environmental impact statement. The Court therefore remanded the matter to NNSA.

In accordance with the Ninth Circuit's remand, NNSA has reviewed the threat to the facility from terrorists and the potential environmental effects that might derive from various terrorist

acts against the facility. Three terrorist acts were considered: 1) a terrorist attack resulting in facility damage; 2) a theft of pathogenic agent by a terrorist from outside of LLNL; 3) a theft of pathogenic agent by an insider. This review finds that:

1) a successful terrorist attack involving facility damage and loss of containment is not expected to occur due to the extensive layered security programs at the LLNL; in any event, the environmental consequences would be bounded by the effects that would occur during catastrophic events or operational accidents;
2) because pathogenic agents are available in nature and other, less secure locations, operation of the LLNL BSL-3 facility would not make pathogenic agents more readily available to an outside terrorist, or increase the likelihood of an attack by an outside terrorist; and
3) the theft of pathogenic materials by an insider from any bio research facility could have very serious consequences; this scenario is not expected to occur at LLNL due to human reliability programs, security procedures, and management controls at the Facility.

NNSA believes that the probability of a successful terrorist attack on the BSL-3 facility is so uncertain that the possibility of such an event cannot be accurately quantified. The EA concludes that the systems and technologies developed by using the proposed facility would likely reduce the probability and consequence of a bio-terrorist act against the public in general.

Since the original EA and its Finding of No Significant Impact were issued in December 2002, NNSA has issued the *Final Site-wide Environmental Impact Statement for Continued Operation of Lawrence Livermore National Laboratory and Supplemental Stockpile Stewardship and Management Programmatic Environmental Impact Statement* (SWEIS, DOE/EIS-0348, DOE/EIS-0236-S3, DOE 2005). Background information in this revised Environmental Assessment has been updated to reflect more current information in the SWEIS if the updated information is pertinent to NNSA determination of the potential effects of the proposed action on human health or the environment. Since 2002, the facility has been constructed and equipment has been installed. To date, no work with BSL-3 material has been performed in the building. As such, DOE acknowledges that the impacts related to construction that are discussed in this document have already occurred. Changes have been made in this revised EA to reflect the "as-built" condition of the facility only if those changes are pertinent to the discussion of impacts from planned operations or reasonably-foreseeable accidents. Other minor changes have been made if guiding regulations or DOE policies have been updated since 2002. Appendices A and B to the original EA was not revised. Appendix C was update as necessary to reflect the comments received on the revised version of the EA.

Vertical bars in the margins indicate changes from the Revised Draft EA made in response to public comments or to update information pertinent to the 9th District Court remand.

Contents

Figures

Tables

ACRONYMS AND ABBREVIATIONS

AAA	American Antiquities Act
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
ABSA	American Biological Safety Association
ACGIH	American Conference of Governmental Industrial Hygienists
AFIP	Armed Forces Institute of Pathology
AIDS	Acquired Immune Deficiency Syndrome
ANSI	American National Standards Institute
APHIS	Animal and Plant Inspection Service
BA	Biological Assessment
BASIS	Biological Aerosol Sentry and Information System
BBRP	LLNL Biology and Biotechnology Research Program
BDRP	Biological Defense Research Program
BLS	Bureau of Labor Statistics
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BMI	Battelle Memorial Institute
BMP	Best Management Practice
BRTA	Biological Risk and Threat Assessment
BSC	Biological Safety Cabinet
BSL	Biological Safety Level
BWC	Biological Weapons Convention
CAA	Clean Air Act
CBNP	Chemical and Biological National Security Program
CDC	Centers for Disease Control and Prevention
CDF	California Department of Finance
CEQ	Council on Environmental Quality
CERCLA	Comprehensive Environmental Response Compensation and Liability Act
CFR	Code of Federal Regulations
CRDEC	Chemical Research Development and Engineering Command
D&D	Decontamination and Decommissioning
DA	Department of the Army
dB	decibel (a measure of noise level)
dBA	A-weighted decibel
DBT	Design Basis Threat
DHS	California Department of Health Services
DNA	Deoxyribonucleic Acid
DoD	U.S. Department of Defense
DOE	U.S. Department of Energy
DOP	Dioctyl phthalate
DOT	U.S. Department of Transportation
DPG	Dugway Proving Ground
EA	Environmental Assessment
EIR	Environmental Impact Report
EIS	Environmental Impact Statement
EIS/EIR	Environmental Impact Statement/Environmental Impact Report

EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ESA	Endangered Species Act
FDA	Food and Drug Administration
FEIS	Final Environmental Impact Statement
FONSI	Finding of No Significant Impact
FY	Fiscal Year
GSA	General Services Administration
HAP	Hazardous Air Pollutant
HEPA	High Efficiency Particulate Air-Purifying
HHS	US Department of Health and Human Services
HID	Human Infective Dose
HID_{50}	Human Infective Dose - 50 percent
HMIS	Hazardous Material Information System
HRSA	HHS, Health Resources and Services Administration
HVAC	Heating, ventilation, and air conditioning
IACUC	LLNL Institutional Animal Care and Use Committee
IATA	International Air Transport Association
IBC	Institutional Biosafety Committee
ID_{50}	Infective Dose - 50 percent
ISMS	Integrated Safety Management System
JH	Johns Hopkins
kW	Kilowatt
LAA	Laboratory Animal Allergy
LANL	Los Alamos National Laboratory
LBNL	Lawrence Berkeley National Laboratory
LBOC	LLNL Biosafety Operations Committee
LD_{50}	Lethal dose at 50 percent mortality
LLNL	Lawrence Livermore National Laboratory
LR/SAT	Laboratory Registration/Select Agent Transfer
LWRP	Livermore Water Reclamation Plant
MCE	Maximum Credible Event
MMWR	Morbidity and Mortality Weekly Report
NAAQS	National Ambient Air Quality Standards
NAI	Nonproliferation, Arms Control, and International Security
NEPA	National Environmental Policy Act
NFPA	National Fire Protection Association
NHPA	National Historic Preservation Act
NIH	National Institutes of Health
NNSA	National Nuclear Security Administration
NSC	National Safety Council
ORPS	Occurrence Report Processing System
OSHA	Occupational Safety and Health Administration
PEIS	Programmatic Environmental Impact Statement
PM	Particulate Matter
PPE	Personal Protective Equipment

RCRA	Resource Conservation and Recovery Act
RDT&E	Research Development Testing and Evaluation
RG	Risk Group
RO	Responsible Official
RNA	Ribonucleic Acid
SA	Supplement Analysis
	Select Agents
SAHRP	Select Agent Human Reliability Program
SNL	Sandia National Laboratories
SNL/CA	Sandia National Laboratory, California
SNL/NM	Sandia National Laboratory, New Mexico
SOP	Standard Operating Procedure
SSH	Suppression Subtractive Hybridization
SWEIS	Site-wide Environmental Impact Statement
SWPP	Storm Water Pollution Prevention
TLV	Threshold Limit Value
UC	University of California
USAMRIID	United States Army Medical Research Institute for Infectious Diseases
USC	United States Code
USDA	United States Department of Agriculture
USDHS	United States Department of Homeland Security
USFWS	United States Fish and Wildlife Service
USPS	United States Postal Service
VEE	Venezuelan Equine Encephalomyelitis
WMD	Weapons of Mass Destruction
WHO	World Health Organization

EXPONENTIAL NOTATION: Many values in the text and tables of this document are expressed in exponential notation. An exponent is the power to which the expression, or number, is raised. This form of notation is used to conserve space and to focus attention on comparisons of the order of magnitude of the numbers (see examples):

1×10^{4}	=	10,000
1×10^{2}	=	100
1×10^{0}	=	1
1×10^{-2}	=	0.01
1×10^{-4}	=	0.0001

Metric Conversions Used in this Document

Multiply	By	To Obtain
Length		
inch (in.)	2.54	centimeters (cm)
feet (ft)	0.30	meters (m)
yards (yd)	0.91	meters (m)
miles (mi)	1.61	kilometers (km)
Area		
Acres (ac)	0.40	hectares (ha)
square feet (ft^2)	0.09	square meters (m^2)
square yards (yd^2)	0.84	square meters (m^2)
square miles (mi^2)	2.59	square kilometers (km^2)
Volume		
Gallons (gal.)	3.79	liters (L)
cubic feet (ft^3)	0.03	cubic meters (m^3)
cubic yards (yd^3)	0.76	cubic meters (m^3)
Weight		
Ounces (oz)	29.57	milliliters (ml)
pounds (lb)	0.45	kilograms (kg)
short ton (ton)	0.91	metric ton (t)

THIS PAGE INTENTIONALLY LEFT BLANK

1.0 PURPOSE AND NEED

1.1 INTRODUCTION

The *National Environmental Policy Act of 1969* (NEPA) requires Federal agency officials to consider the environmental consequences of their proposed actions before decisions are made. In complying with NEPA, the United States (U.S.) Department of Energy (DOE), National Nuclear Security Administration (NNSA[1]) follows the Council on Environmental Quality (CEQ) regulations (40 *Code of Federal Regulations* [CFR] 1500-1508) and DOE's own NEPA implementing procedures (10 CFR 1021). The purpose of an environmental assessment (EA) is to provide Federal decision-makers with sufficient evidence and analysis to determine whether to prepare an Environmental Impact Statement (EIS) or issue a Finding of No Significant Impact (FONSI). This EA has been prepared to assess environmental consequences resulting from the construction and operation of a Biosafety Level 3 (BSL-3) laboratory[2] facility within the boundaries of the Lawrence Livermore National Laboratory (LLNL), Livermore, CA (Figure 1-1). LLNL is one of the national security laboratories under the authority of the Under Secretary for Nuclear Security of the NNSA who serves as the Administrator for Nuclear Security and Head of the NNSA (50 USC Chapter 41, § 2402(b)).

The objectives of this EA are to (1) describe the underlying purpose and need for NNSA action; (2) describe the Proposed Action and identify and describe any reasonable alternatives that satisfy the purpose and need for NNSA action; (3) describe baseline environmental conditions at LLNL; (4) analyze the potential indirect, direct, and cumulative impacts to the existing environment from implementation of the Proposed Action and other reasonable alternatives; and (5) compare the impacts of the Proposed Action with the No Action Alternative and other reasonable alternatives. For the purposes of compliance with NEPA, reasonable alternatives are identified as being those that meet NNSA's purpose and need for action by virtue of timeliness, appropriate technology, and applicability to LLNL.

The EA process also provides NNSA with environmental information that can be used in developing mitigative actions, if necessary, to minimize or avoid adverse effects to the quality of the human environment and natural ecosystems should NNSA decide to proceed with implementing the construction and operation of a BSL-3 facility at LLNL. Ultimately, the goal of NEPA and this EA is to aid NNSA officials in making decisions based on an understanding of environmental consequences and taking actions that protect, restore, and enhance the environment.

[1] The NNSA is a separately organized agency within DOE established by Congress in 2000 under Title 50 United States Code Chapter 41, Subchapter I, Section 2401.

[2] A biosafety level or BSL is assigned to an agent based upon the activities typically associated with the growth and manipulation of the quantities and concentrations of infectious agents required to accomplish identification or typing as determined by the Centers for Disease Control (CDC) and National Institutes of Health (NIH). Additional information about the various BSL assignments is provided in later sections and within Appendix A of this EA.

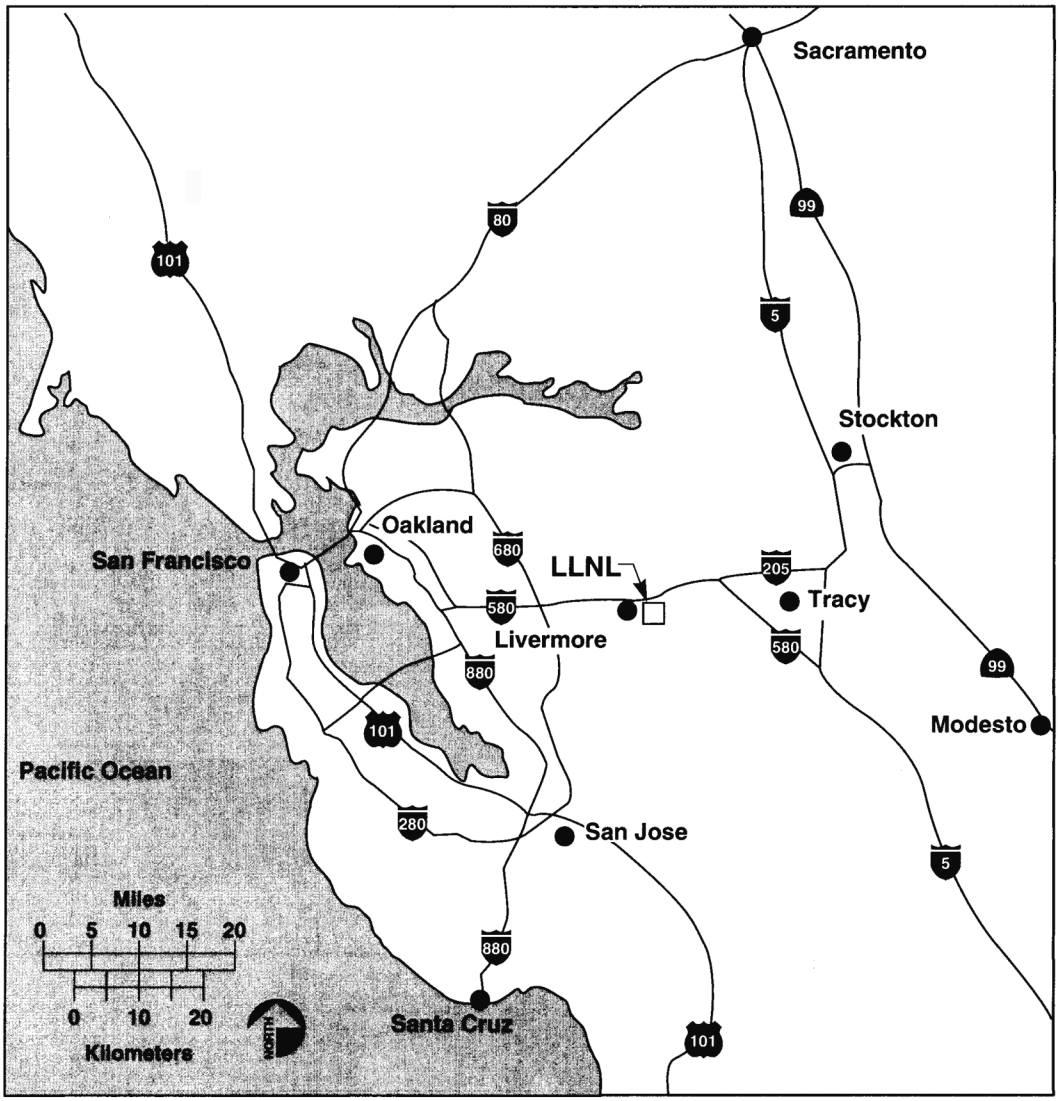


Figure 1-1. Location of Lawrence Livermore National Laboratory (LLNL)

1.2 BACKGROUND

The LLNL Livermore site lies just outside the boundary of Livermore, California. It occupies a total area of approximately 1.3 sq miles (821 acres), and is about 40 miles east of San Francisco at the southeast end of the Livermore Valley in southern Alameda County, California. The City of Livermore's central business district is located about 3 miles to the west. Figure 1-1 and Figure 1-2 show the regional location of the LLNL Livermore site and its location with respect to the City of Livermore. Lawrence Livermore National Laboratory (LLNL) is a U.S. Department of Energy national laboratory operated by the University of California (UC). Since the publication of this EA, a new M&O contractor for LLNL has been selected, Lawrence Livermore National Security, LLC (LLNS). LLNL was founded in September 1952 as a second nuclear weapons design laboratory to promote innovation in the design of our nation's nuclear stockpile through creative science and engineering. LLNL has also become one of the world's premier scientific centers, where cutting-edge science and engineering in the interest of national security

is used to break new ground in other areas of national importance, including energy,

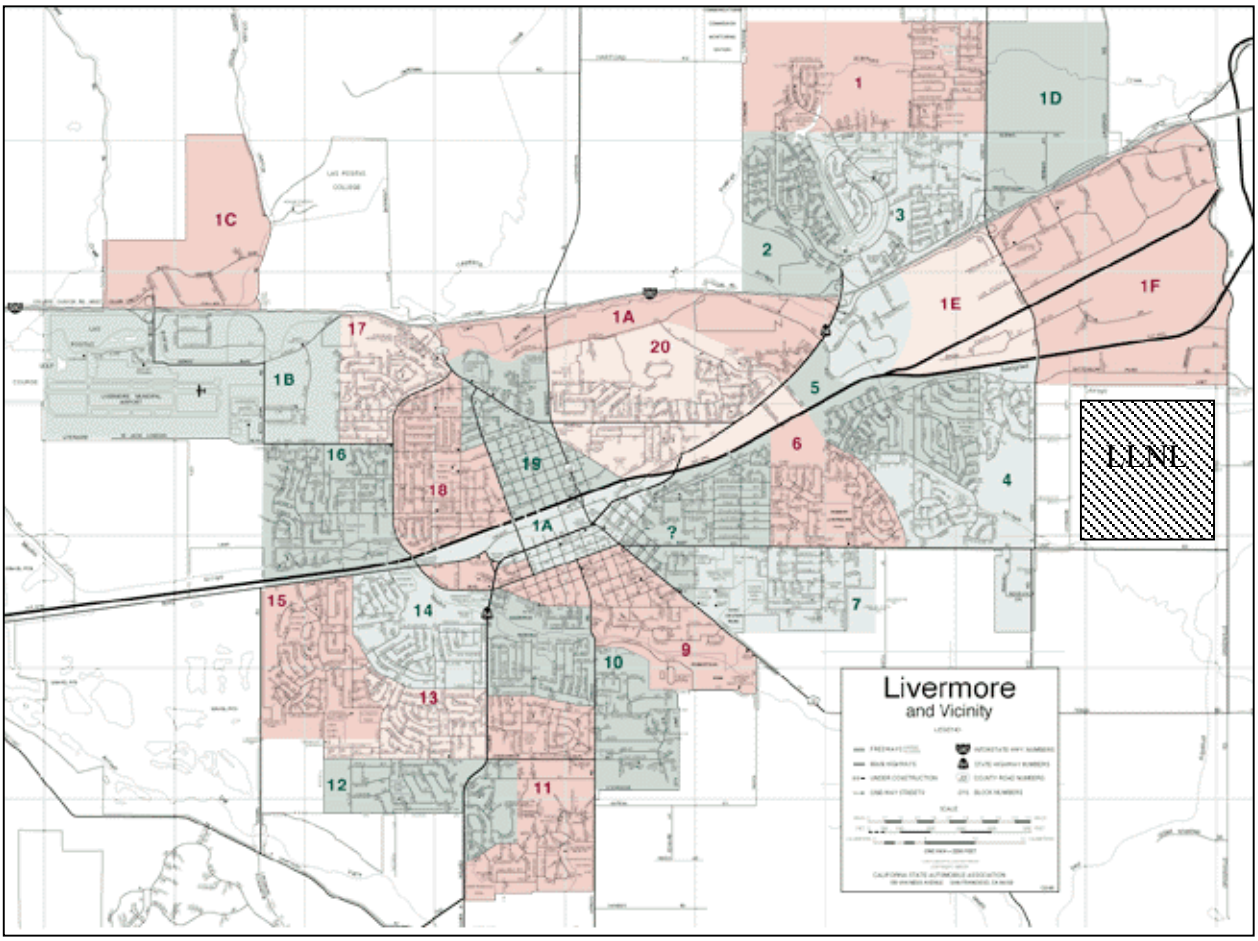


Figure 1-2. Location of LLNL with respect to the City of Livermore, CA

biomedicine, and environmental science.

Current NNSA mission-support work at LLNL includes research and development work performed for a variety of programs within the NNSA, other DOE programs, as well as cost-reimbursable work that is identified as "work for others." This designation, "work for others," encompasses non-DOE sponsored work performed in support of other Federal agencies, universities, institutions, and commercial firms, which is compatible with the NNSA mission work conducted at LLNL and which cannot reasonably be performed by the private sector. Within DOE, the NNSA mission is "(1) To enhance United States national security through the military application of nuclear energy; (2) To maintain and enhance the safety, reliability, and performance of the United States nuclear weapons stockpile, including the ability to design, produce, and test, in order to meet national security requirements; (3) To provide the United States Navy with safe, militarily effective nuclear propulsion plants and to ensure the safe and reliable operation of those plants; (4) To promote international nuclear safety and nonproliferation; (5) To reduce global danger from weapons of mass destruction (WMD); and (6) To support United States leadership in science and technology" (50 USC Chapter 41, § 2401(b)). Work

conducted at LLNL provides support to these NNSA missions, with a special focus on national security.

NNSA has the responsibility for national programs to reduce and counter threats from weapons of mass destruction (nuclear, biological, and chemical weapons). Activities conducted in this area include assisting with control of nuclear materials in states of the former Soviet Union, developing technologies for verification of the Comprehensive Test Ban Treaty (September 1996), countering nuclear smuggling, safeguarding nuclear materials and weapons, and countering threats involving chemical and biological agents.

The DOE Chemical and Biological National Security Program (CBNP) was initiated in fiscal year (FY) 1997 to engage the DOE and its laboratories more fully in the development and demonstration of new technologies and systems to improve U.S. domestic preparedness and response capabilities to chemical and biological attacks. The CBNP is a needs-driven program focused on addressing the highest priority area to counter chemical and biological threats against the people and economy of the United States of America as well as the threat against democracy and freedom. The CBNP was established in response to the *Defense Against Weapons of Mass Destruction Act* passed by Congress in 1996 (50 USC § 2301).

DOE and the national security laboratories have a long history of supporting nonproliferation and national security policy. As part of its primary nuclear science and technology mission, DOE has developed extensive capabilities in chemistry, biology, materials and engineering science, computations, and systems engineering at these laboratories. These capabilities, in areas such as genomic sequencing, development of new deoxyribonucleic acid (DNA[3])-based diagnostics, advanced modeling and simulation, and microfabrication technologies, as well as the joining of these capabilities with expertise in nonproliferation and national security, form the basis of NNSA's role in combating the chemical and biological threat. In addition to the chemical and biological nonproliferation activities supported by this program, the national security laboratories conduct work in chemical and biological defense research for other government agencies.

Since this EA was originally published, some of DOE's missions relating to biological security have been transferred to the Department of Homeland Security (DHS). However, DOE and LLNL continue to support this critical mission by performing work for the DHS on a "work for others" basis. The Homeland Security Act of 2002 authorizes DHS to access the capabilities of DOE's laboratories and other sites to further DHS mission objectives. In this revised document, references to DOE or NNSA missions should be understood to include work conducted on behalf of DHS in support of their mission objectives.

LLNL has been assigned research and development activities in support of these NNSA responsibilities. The LLNL Biology and Biotechnology Research Program (BBRP) (now part of the Chemistry, Materials, Earth, and Life Sciences Directorate) has been assigned the primary responsibility for conducting work related to biological science research including work with national health security issues and emerging diseases. Program objectives include understanding genetic and biochemical causes of disease, countering biological terrorism, bioengineering

[3] DNA is the polymeric deoxyribonucleic acid that determines the hereditary information in cells.

research, and developing and applying computational biology capabilities. Most of the on-site work is conducted in the Building 360 Complex area (Figure 1-3). Current research performed at this complex includes structural, molecular, and cellular biology, biophysics, biochemistry, and genetics research.

The BBRP work in the biosciences arena at LLNL has been ongoing for more than 40 years, and is conducted according to the accepted national standards for biosafety level (BSL)-1 and -2 work that have been developed by the U.S. Department of Health and Human Services, Public Health Service, through their subsidiary organizations, the CDC and the NIH. Details regarding BSLs -1, -2, and -3 and specific information and requirements for work in microbiological laboratories are provided in Appendix A of this EA. In addition, prior to commencement of any

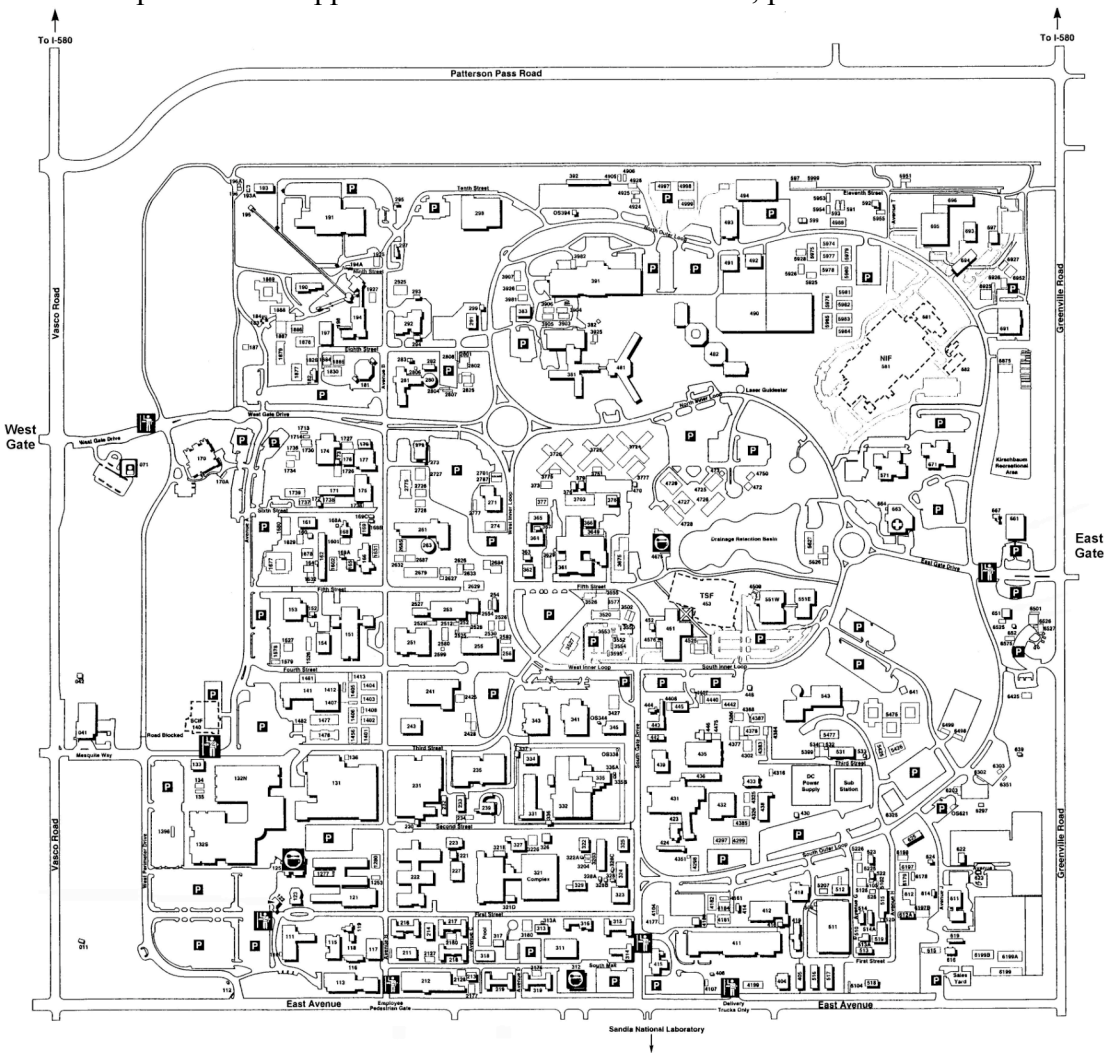


Figure 1-3. Map of LLNL showing the location of the Building 360 Complex Area (within the dashed line)

LLNL experiments involving biological agents[4], work is reviewed and must be approved by the LLNL Laboratory Biosafety Operation Committee (LBOC). Certain projects must also be

[4] Biological agents or bioagents are organisms or the product of organisms that present a health risk to humans. These can be bacterial, fungal, parasitic, rickettsial, or viral agents, or prions.

reviewed and approved by the LLNL Institutional Biosafety Committee (IBC), which is made up of LLNL staff members, UC and community health care providers, a DOE Federal member, and at least two members of the public. The IBC typically meets in the Building 361 Complex several times per year, depending on demand. In general, BSL-2 facilities are used for working with a broad spectrum of biological agents (or bioagents) or biological toxins[5] commonly present in the community and may be associated with human disease of moderate severity. Facilities using CDC and NIH standards have demonstrated safe and secure working conditions with infectious agents. According to these standards for BSL-2 (CDC 1999) laboratories, the primary hazards to personnel working with agents at this level relate to accidental exposures through skin punctures or contact with mucous membranes, or ingestion. The organisms routinely manipulated at BSL-2 are not known to be transmissible, person-to-person by the airborne pathway. Examples of diseases include Hepatitis, measles, and salmonellae. Limited access, separated from public areas with posted BSL-2 biohazard signs, waste decontamination facilities, together with standard and special microbiological practices, are required for these laboratories. Common examples of BSL-2 facilities are those located in hospitals, medical schools, veterinary schools, biology research institutions, and dental offices.

According to their standard for BSL-3 (CDC 1999), the primary hazards to personnel working with agents at this level relate to accidental injections, ingestion, and exposure through airborne pathway. In BSL-3, more emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to potentially infectious aerosols. There are currently over 1350 BSL-3 laboratory facilities in the United States at various non-DOE sites (GAO 2007). BSL-3 laboratory facilities are specifically designed and engineered for work with bioagents with the potential for aerosol transmission that may cause serious or potentially lethal disease by inhalation if left untreated (such as the bacteria responsible for causing tuberculosis in humans). Examples of common BSL-3 facilities include hospital surgical suites, clinical, diagnostic, and teaching laboratories associated with medical or veterinary schools, and university research and development laboratories. Requirements of operating a BSL-3 facility (CDC 1999) are detailed in Appendix A.

Current research and technology development work conducted at LLNL targets both the reduction of the national threat from terrorism using biological weapons and enhances the Nation's public health capabilities. For example, in support of these responsibilities LLNL has developed the Biological Aerosol Sentry and Information System (BASIS) for early detection and rapid response to biological attack, conducts "expression studies" of *Yersinia pestis*, the causative bacterial agent in plague to understand the mechanisms of virulence, and performs "suppression subtractive hybridization" (SSH) to study the fundamental biology of microbes through DNA segmentation and similar-strain comparison. This current research and technology development work is focused on the development of scientific tools to identify and understand the pathogens of medical, environmental, and forensic importance.

The importance of work performed by NNSA laboratories in bioscience research and development in support of the national security WMD nonproliferation mission is increasing. This mission is to develop, demonstrate, and deliver technologies and systems to improve domestic defense capabilities and, ultimately, to save lives in the event of a chemical or

[5] Biological toxins are toxic chemicals of biologic origin and are not self-replicating.

biological attack. The threat presented by terrorists and rogue nations to the American people and our allies, including military personnel, amplifies the need for threat reduction research. Current work at LLNL in bioscience research is limited to BSL-2. Pending and future work in support of the DOE, NNSA, and DHS national security missions requires specialized facilities to safely and securely handle and store infectious organisms beyond that which can be provided by BSL-2. DOE does not currently have under its administrative control within the DOE complex any microbiological laboratory facility capability beyond BSL-2, but BSL-3 facilities are proposed both at LLNL (as outlined in this EA) and at Los Alamos National Laboratory (LANL) (DOE 2002b).

Additional information regarding the DOE and NNSA mission areas of work conducted at LLNL is presented in the *Final Environmental Impact Statement and Environmental Impact Report for Continued Operations of Lawrence Livermore National Laboratory and Sandia National Laboratories, Livermore, August 1992* (DOE/EIS-0157) (DOE 1992), its associated Supplement Analysis (SA) (DOE 1999), and the *Final Site-wide Environmental Impact Statement for Continued Operation of Lawrence Livermore National Laboratory and Supplemental Stockpile Stewardship and Management Programmatic Environmental Impact Statement* (SWEIS, DOE/EIS-0348, DOE/EIS-0236-S3, DOE 2005).

1.3 PURPOSE AND NEED FOR AGENCY ACTION

DOE conducts bioscience work in support of its biology and biotechnology research programs, work for other agencies, and work in support of CBNP. The NNSA CBNP mission is to "develop, demonstrate and deliver technologies and systems to improve domestic defense capabilities and, ultimately, to save lives in the event of a chemical or biological attack."

In order to meet these mission requirements, it is necessary to expand some existing capabilities to test the understanding and effectiveness of research on infectious agents and biotoxins, particularly those associated with potential bioweapons threats. Efficient execution of the NNSA mission therefore, also requires the capability to handle operations involving small-animal (rodent) challenges of bioagents (and possibly biotoxins) and the ability to produce small amounts of biological material (enzymes, DNA, ribonucleic acid[6] [RNA], etc.) using infectious agents and genetically modified agents under conditions that would require management of the facility at the BSL-3 level.

This capability does not currently reside within DOE/NNSA facilities, but some of the research is carried out for the LLNL Nonproliferation, Arms Control, and International Security (NAI) Directorate primarily by the BBRP using external (private-sector and University) laboratories to conduct the BSL-3 level components of the research. The nature of BSL-3 work requires efficient sample processing, handling of a variety of organisms concurrently, and assurance of sample security and integrity. NNSA's mission requirements for sample integrity necessitates that the chances of cross-contamination and degradation of samples be minimized by reducing excessive handling and transportation. The several key off-site BSL-3 facilities that conduct work for LLNL in support of NNSA, are often heavily committed to other projects or tailored to

[6] Ribonucleic acid or RNA is a generic term for a group of natural polymers present in all living cells directly involved with protein synthesis.

work with microorganisms not of specific interest to NNSA. This has especially become an issue since September 11, 2001. Because of this these laboratories are unlikely to be able to provide the quick response that may be necessary to support the NNSA need.

An on-site BSL-3 facility would provide safe and secure manipulation and storage of infectious microorganisms at a time when these issues are imperative to national security. In order to more effectively utilize and capitalize on existing onsite facilities and capabilities at LLNL, including informatics and DNA sequencing capability, and to ensure the quality, timeliness, integrity and security of microbiological work, NNSA needs BSL-3 laboratory capability within the boundaries of this national laboratory.

1.4 PUBLIC INVOLVEMENT

The Draft EA was originally made available for public comment from July 24 through August 23, 2002. The comment period was extended through September 7, 2002.

The revised document was made available for a 30 day comment period beginning April 11 and ending May 11, 2007. No comments received were excluded from the record. All comments were accepted even if they were received after the 30 day period.

1.5 COMMENT SUMMARIES AND NNSA RESPONSES

The full text of the comments received by NNSA on the Revised Draft EA by stakeholders and members of the public are included in Appendix C-2 of this EA. Where comments were duplicated, as in the presentation of form-type letters, only one is shown in its entirety. Many of the topics generated from public responses are of broad interest or concern and were categorized into twelve general issues which comprise the twelve sections in Appendix C-1. Comments and concerns voiced by the commentors were addressed through changes made to the document text to the extent practicable. Some commenters raised issues that are not pertinent to the NEPA review. These were also addressed to the extent practicable. The following general issues are discussed in the appendix:

1. NEPA Compliance: Documentation/Review Level
2. Safety of Laboratory Operations
3. Defensive vs. Offensive-oriented Research
4. Compliance with the Biological Weapons Convention
5. Public Health and Safety, and Worker Safety Issues
6. Accident Analysis
7. Threat of Terrorist Attack/Sabotage
8. Transportation Safety
9. Purpose and Need
10. Adequacy of Alternatives Analysis
11. Waste Disposal
12. Timeline for the BSL-3 Facility
13. Oversight
14. Public Comment Period and Public Hearings

Appendix C includes only those comments received on the Revised EA. Comments previously received on the original document have been left out to reduce the length of the appendix. The original responses from the 2002 EA have been revised or updated where public comments on the Revised Draft EA provided new information pertinent to the proposed action or expressed concerns that were not responded to previously.

2.0 DESCRIPTION OF PROPOSED ACTION AND ALTERNATIVES

Section 2.1 describes the Proposed Action for the EA that would allow NNSA to meet its purpose and need for agency action. Two additional alternatives are presented in Section 2.2 and 2.3, respectively. The No Action Alternative is presented in Section 2.4 as a baseline for comparison with the consequences of implementing the Proposed Action. Alternatives that were considered in this EA but were not analyzed further are discussed in Section 2.5, and related actions are identified in Section 2.6.

Readers of this revised document should note that since the original Environmental Assessment and its associated Finding of No Significant Impact were issued in December 2002, the facility has been constructed and equipment has been installed. This document has been revised to address the issues regarding terrorist attacks pursuant to the Ninth Circuit Court's remand. NNSA acknowledges that the impacts related to construction that are discussed in this document have already occurred. Changes have been made in this revised EA to reflect the "as-built" condition of the facility only if those changes are pertinent to the discussion of impacts from proposed operations or reasonably-foreseeable accidents.

2.1 PROPOSED ACTION TO CONSTRUCT AND OPERATE A BSL-3 FACILITY AT LLNL

NNSA proposes to construct and operate a BSL-3 facility at LLNL for the purpose of conducting biological research projects involving indigenous or exotic agents which may cause serious or potentially lethal or debilitating effects on humans, plants, and animal hosts, therefore, potentially impacting human health as well as agriculture, food, and other industries. LLNL's existing BSL-2 laboratory capability which cannot be used to perform this work is primarily located in the Building 360 Complex area (see Figure 1-3). As proposed, the BSL-3 facility would be an essential component for future advanced biological sciences research and development performed by LLNL's staff but would not replace the other biological laboratory capabilities at LLNL. The BBRP would continue to support current biological sciences initiatives at LLNL through the existing BSL-2 laboratories. The proposed facility (Figure 2-1) would be a permanent modular unit that would be constructed off-site and assembled on-site near the northwest corner of Building 361. It would have the same life expectancy as a facility constructed on-site.

The construction would be permanent and meet applicable building code, and required structural, seismic, plumbing, electrical, and fire standards. The proposed facility would include three BSL-3 laboratory rooms, one of which would be capable of holding rodents. The building would include clothes-change and shower rooms, a mechanical room, and some storage space, but no office space. When complete, the BSL-3 facility would be about 1,500 ft^2 (135 m^2) in size and would normally be occupied by no more than 6 workers. As currently projected, these staff

members would come from the adjacent Building 360 Complex laboratory facilities (Figure 2-1) with no requirement for permanent relocation. Any additional staffing needed to support BSL-2 work previously done by workers who would be performing BSL-3 work may be made up by hiring locally or regionally, as necessary, to find qualified individuals.

The BSL-3 facility would be designed with a lifetime expectancy of 30 years (minimum) of operation. During the operational life of the building, the performance of routine maintenance actions would be expected. At the end of the facility's useful life, final decontamination and demolition would be performed as needed.

2.1.1 Proposed BSL-3 Facility Location and Construction Measures[7]

The proposed location is in the current parking area and access-drive directly adjacent to (east of) building B-365 and northeast of the intersection of Fifth Street and West Inner Loop (see Figure 2-1). Approximately 20 parking spaces of the paved current parking area would become

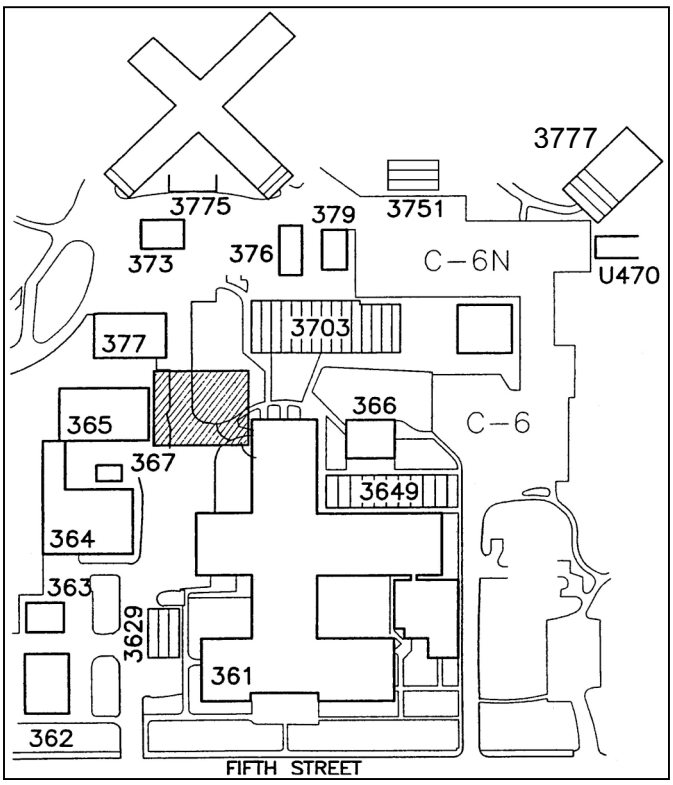


Figure 2-1. Map of the Building 360 Complex Area showing the location of the proposed BSL-3 facility (cross-hatched area)

permanently unavailable for use due to the footprint of the building and it may be necessary to redirect part of the parking access driveway.

[7] As discussed in Section 2.0, construction of the facility has already occurred.

The footprint of the proposed building would be less than one-quarter of an acre. Utilities necessary for construction and operation of the BSL-3 facility would be available within 50 ft (15 m) of the proposed construction site facility. These include potable water, natural gas, steam, sewer, electricity, and telephone service. Some minor trenching (at depths less than about 4 ft [1.3 m]) would be required to bring those utilities to the site.

Construction Measures[8]: As noted above, the project construction site would be at a location that has previously been cleared of buildings or structures and is within existing paved parking areas. No undeveloped (so called "green field") areas would be involved. No construction would be conducted within a floodplain or a wetland. The building would not be constructed over a known geologic fault or vertical displacement of a fault line, nor would it be sited within 50 feet of such a condition. No construction would be conducted within a solid waste management unit.

The BSL-3 facility building would be designed in accordance with guidance for BSL-3 laboratories established by the CDC and NIH (CDC 1999, NIH 2001). The CDC, which is part of the Department of Health and Human Services, provides guidelines for the operation of BSL-3 facilities, registers facilities that will access, use and transfer select agents, and then periodically inspects these facilities during operation. DOE Order O420.1 (DOE 1996b) which addresses natural phenomena hazard mitigation for non-nuclear facilities would be considered in preparing the final design criteria for seismic, wind and flooding events.

Sustainable design features would allow the structure to operate with improved electric and water use efficiency and would incorporate recycled and reclaimed materials into the construction as much as practicable while still meeting the requirements specified by CDC for laboratory interiors. For example, the facility could incorporate building and finish materials and furnishings made of reclaimed and recycled materials, low-flow lavatory fixtures to minimize potable water use, and energy-efficient lighting fixtures and equipment to reduce electric consumption. Where possible, the finished landscaping of the involved construction area would utilize non-potable water, reused and recycled materials, and native plant species.

Clearing or excavation activities during site construction have the potential to generate dust and encounter previously buried materials. If buried materials or remains of cultural or paleontological significance were encountered during construction, activities would cease until their significance was determined and appropriate subsequent actions taken in accordance with the National Historic Preservation Act (NHPA, 16 USC 470) or the American Antiquities Act (AAA, 16 USC 430). Standard dust suppression methods (such as water spraying) would be used onsite, if needed, to minimize the generation of dust during all phases of construction activities.

All construction work would be planned and managed to ensure that standard worker safety goals would be met. All work would be performed in accordance with good management practices, with regulations promulgated by the Occupational Safety and Health Administration (OSHA, 29 CFR 1910 and 29 CFR 1926), in accordance with various DOE orders involving worker and site safety practices, and in accordance with the LLNL Environment, Health and

[8]As discussed in Section 2.0, construction of the facility has already occurred.

Safety Manual (LLNL 2001c). The construction contractor would be prohibited from using chemicals that generate *Resource Conservation and Recovery Act* (RCRA)-regulated wastes (40 CFR 261). Engineering best management practices (BMPs) would be implemented at the building site chosen, as part of a Storm Water Pollution Prevention (SWPP) Plan executed under a National Pollutant Discharge Elimination System construction permit. These BMPs may include the use of hay bales, plywood, or synthetic sedimentation fences with appropriate supports installed to contain any excavated soil and surface water discharge during construction of the BSL-3 facility. After the facility is constructed, mounds of loose soil would be tested for previous contaminants, removed from the area, and either reused or disposed of appropriately.

During site preparation and construction, noise levels (for short time periods) would be consistent with those expected from the construction of single-story frame non-residential structures using metal studs and cross members. The use of welding equipment, air compressors, riveting tools, and heavy equipment is reported to range from 65 to 125 dBA[9] continuous or intermittent noise. Power-actuated tools (for example, those for setting fasteners into concrete) can go up to 139 dBA of impact-type noise near the point of generation (ACGIH 2000).

Vehicles and heavy machinery (such as front-end loaders, dump trucks, cranes, and cement mixer trucks) would be used onsite during the construction phase. These vehicles would operate primarily during the daylight hours and would be left onsite overnight. If needed, temporary task lighting would be used. Wastes generated by site preparation and construction activities would be expected to be nonhazardous.

Construction of the BSL-3 facility is estimated to start in FY 2003 and take several months to complete. Construction materials would be procured primarily from local California suppliers. Construction workers would be drawn from local communities or would be derived from the current in-house LLNL staff.

2.1.2 BSL-3 Facility Description and Operations

Facility Description: The proposed BSL-3 facility would be a one-story building with about 1,500 ft^2 (135 m^2) of floor space (Figure 2-2) housing three BSL-3 laboratories (one with rodent handling and maintenance capability), showers, sinks, lavatories, and mechanical and electrical equipment areas. The BSL-3 facility would most likely be constructed using concrete footing and stem walls with concrete slab-on-grade floors. Walls would be steel stud framed and the roof construction would consist of metal decking over steel bar joists. The exterior walls would have an application of stucco and the painting of the building would be visually consistent with surrounding structures. The interior surfaces of walls, floors, and ceilings of the BSL-3 laboratory areas would be constructed for easy cleaning and disinfection. The walls would be finished with an easily cleanable material with sealed seams, resistant to chemicals and disinfectants normally used in such laboratories. Floors would be coated and slip-resistant. All penetrations in floors, walls, and ceiling surfaces would be sealed, or capable of being sealed to facilitate disinfection, to aid in maintaining appropriate ventilation system air pressures, and to keep pests out. Laboratory furniture would be capable of supporting anticipated loading and use,

[9] dBA refers to sound level in decibels measured on a sound level meter using the A-weighted scale as established by the American National Standards Institute (ANSI, 1983)

and bench tops would be impervious to water and resistant to moderate heat, chemicals used, and disinfection solutions. Spaces between benches, cabinets, and equipment would be accessible for cleaning with disinfectants.

Each of the three BSL-3 laboratories would have at least one Class II Type A-2 biological safety cabinet[10] (BSCs) (Figure 2-3). Class II BSCs provide their own airflow, have High Efficiency Particulate Air-Purifying (HEPA)[11] filtration internally within the cabinet and would be designed to provide personal, environmental, and test material protection. Exhaust air from the BSCs would exit the room via the thimble-type connection to HEPA filters in the mechanical rooms, then outside the building. With the use of Class 11, Type A-2 BSCs, some room air from outside the BSC may exit directly (through the thimble connection) to the building exhaust system without first going through the BSC. All BSC air and room air would be 100 percent exhausted to the outside through the building heating, ventilation, and air conditioning (HVAC) and HEPA filtration system (air exhausted from BSCs is doubly-filtered). Class II Type A-2 BSCs are designed to operate at a minimum inward flow of a 100 linear ft per min (30.5 linear m per min) at the face opening (CDC 2000b). BSCs would be located away from doors, room supply louvers, and heavily

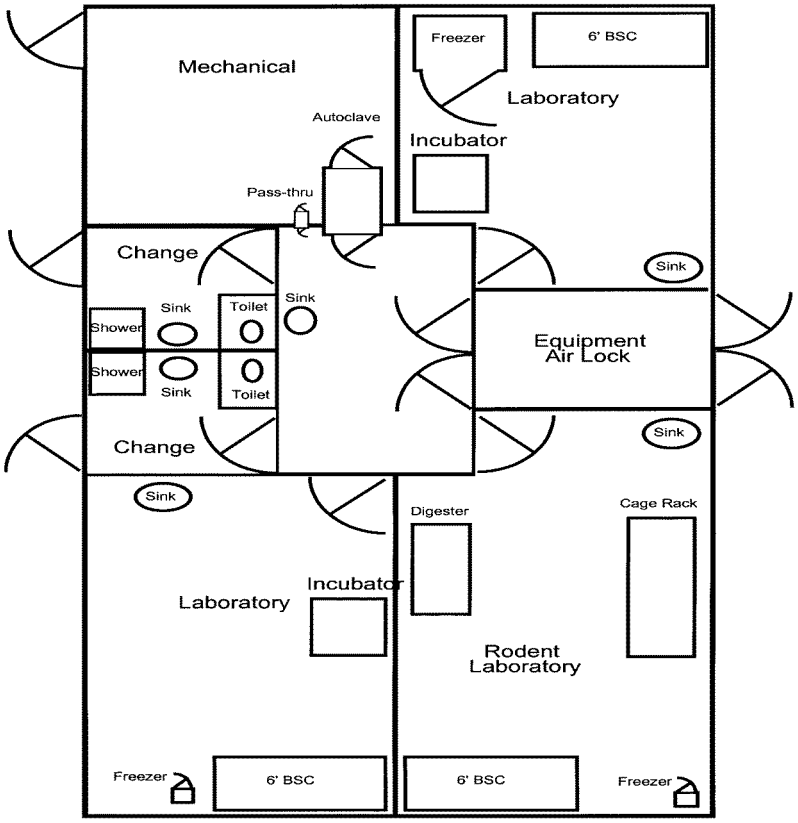


Figure 2-2. Conceptual floor plan for the proposed BSL-3 facility at LLNL (not to scale) (The As-Built facility does not significantly vary from this drawing.)

[10] A BSC (biosa :ing safely with infe

[11] HEPA filter is a disposable, extended-medium, dry-type filter with a particle removal efficiency of no less than 99.97 percent for 0.3-micron particles.

Figure 2-3. Photo of a NUAIR - Class II Type A-2 BSC[12] with Thimble Connection

traveled laboratory areas. BSC interiors would be cleaned by use of appropriate methods and could include ultraviolet light or chemical disinfection. BSCs would be tested and certified annually and after installation, repair, or relocation in accordance with CDC guidance (CDC 2000b).

No windows would be installed in the BSL laboratory's exterior walls. Non-opening observation windows would be placed on interior doors. Centrifuges or other equipment that have the potential to produce aerosols would be operated in BSCs or with appropriate combinations of personal protective equipment (PPE), physical containment, or control devices. Vacuums would be provided to critical work areas using portable vacuum pumps properly fitted with traps and HEPA filtration.

Each laboratory would also contain at least one refrigerator or freezer. Biological materials would be stored either in regular refrigerators for short-term use or in ultra-low temperature mechanical freezers operating between –50 and –85°C for long-term sample storage or archiving.

The BSL-3 laboratory used for rodent handling would have a tissue digestor for the purpose of sterilizing all animal tissues at the conclusion of each study involving small rodents. Figure 2-4 shows an example of a tissue digestor unit that could be used. The digestor would use an alkaline hydrolysis process at an elevated temperature to convert all of the organic material (as well as infectious microorganisms) into a sterile aqueous solution of small peptides, amino acids, sugars, and soaps. The alkali would be used up in the process. Aside from the aqueous solution, the only byproducts would be mineral (ash) components of the bones and teeth.

[12] The use of a trade name does not constitute an endorsement nor does it indicate that the product would be purchased. This is only shown to be representative of the type of equipment that would be used.

The BSL-3 laboratory used for rodent testing would also contain an rodent caging system similar to that shown in Figure 2-5. These ventilated cages would be pressurized with HEPA-filtered air, thus reducing both ammonia and carbon dioxide. The negative pressurization would provide

Figure 2-4 Photo of a Waste Reduction Inc. ™ small-capacity tissue digestor[1]

Figure 2-5. Photo of an Allentown Caging Equipment Co.™ BioContainment Unit for small animals[10]

continuous quarantine status, protecting personnel and preventing contact with the other rodents in the cage rack. A maximum of 100 rodents, mainly mice (some rats and possibly guinea pigs), would be used at any one time. Once a rodent would be used in testing it would never leave the cage except for cage-cleaning and inspection which would occur only in the confines of the BSCs. Once removed from a cage the rodents would only be placed back into a clean cage. The dirty cage and its contents would be autoclaved[13] prior to reuse. All rodents used would be supplied by the already-existing rodent quarantine facility located and operated in an adjacent building. The cage rack would be restrained from toppling over by resisting about 1g of lateral acceleration. Cage latches have been tested to 2g's of pull force.

Some rodents would be exposed to infectious agents in the BSC through inhalation via a device known as a collision nebulizer. This device creates aerosol particles of known size (depending upon the specific nozzle used) to which rodents would be exposed through a nose-piece. The nebulizer consists of a 32-ounce Pyrex™ glass liquid storage container with a "T-shaped" stainless steel aerosol jetting-device operated by compressed air. The device would only be used in the BSC and would be chemically disinfected in place after use. Once exposed, the rodent would (while still in the BSC) be placed directly into a clean cage and placed back into the ventilated cage rack for observation.

Physical security of the facility building would be implemented commensurate with the level of work being performed. The facility safeguards would be based upon a security analysis conducted during the project planning stage. As in all facilities managed at LLNL, security in the proposed facility would be maintained by limiting access to only authorized DOE-badged personnel. Employee qualifications and training requirements are described in CDC-NIH guidelines (CDC 1999) along with a discussion of appropriate management of security concerns.

Fire suppression for the BSL-3 facility would be provided by a standard wet-pipe fire sprinkler system. Water flow alarms would be connected to LLNL's fire alarm monitoring station so that designated responders would be notified. Water used for fire suppression that might become pooled on the building floor would be discharged from the floor drains to a retention tank system, for containment, characterization, and disinfection as needed, prior to discharge to the sanitary sewer system.

Two HEPA filter banks in series in the building exhaust system would filter all room air one-time-through and provide secondary filtration for exit air from the BSCs. Filter banks could be switched or alternated to permit disinfection and filter replacement. Routine maintenance of the filter banks would be conducted by certified technicians, including replacement of the filters. Replaced filters would be chemically sterilized prior to disposal. There would be only one electrical room with access for maintenance from the exterior of the building. The BSL-3 facility would employ lightning protection designed to meet the requirements of the National Fire Protection Association (NFPA 1997 and 2000). Entry of personnel into the BSL-3 laboratories would be through the change rooms which would serve as self-closing double-door access.

[13] An autoclave is an apparatus using superheated steam under pressure to kill or sterilize microorganisms

The air-handling systems, including the heating, ventilation and air conditioning (HVAC) systems, would be designed in accordance with CDC guidelines to provide for individual temperature and ventilation control zones as required in the BSL-3 laboratories and support areas. A ducted exhaust HVAC system would draw air into the BSL-3 laboratories from the adjoining areas toward and through the BSL-3 laboratories areas with no recirculation from the BSL laboratories to other areas of the building. The BSL-3 laboratories would be under the most negative pressure with respect to all other areas of the building. Air discharged from the BSL-3 facility would be dispersed well above the roofline and away from adjacent building air intake ducts. Direction of airflow into the laboratories and the BSCs would be verifiable with appropriate gauges and an audible alarm system to notify personnel of HVAC problems or system failure. Operation of all equipment would be designed to avoid interference with the air balance of the BSCs or the designed airflow of the building.

In the event of a power outage, all biological materials would immediately be placed in a "safe" configuration, such as confinement or chemical disinfection. The HVAC systems would be supplied with backup power from an adjacent facility diesel generator to minimize power supply interruption. Exhaust stacks would be placed well above the roof (10 ft (3 m) or greater) and away from the buildings' air intakes.

Should power be lost to the building and the HVAC system, the air supply system would shut down and zone-tight dampers would close automatically to prevent air migrating from the laboratory areas to other areas of the building.

All research-related biological waste from the BSL-3 laboratory would undergo either autoclaving or chemical disinfection. These wastes would be discharged from laboratory sinks, floor drains, or the tissue digestor and would be held and disinfected in retention tanks before being discharged into the sanitary sewer system. Tap water entering the BSL-3 laboratories through spigots in the sinks or shower heads would have backflow preventers to protect the potable water distribution system from contamination. Biological cultures could be disposed of in the sinks after undergoing treatment with chemical disinfectants for an appropriate amount of time.

The electrical requirements for the BSL-3 facility would be about 60 kilowatts (kW); the building would be attached to an adjacent building which has a diesel generator sized to supply laboratories with electric power in the event of a power failure from the supply grid system. In the event of a power outage, the generator would immediately supply electricity to the laboratories so that workers could shut down the laboratories safely.

Parking would be in nearby common-use lots with handicapped-accessible parking near the building entry (ANSI 1998).

Operations: The BSL-3 facility would be operated according to all guidance and requirements established by the CDC and NIH (CDC 1999), DOE, and LLNL. Prior to operating the facility using select agents, the facility would be registered with a unique registration number obtained from the Secretary of the US Department of Health and Human Services (HHS) according to the *U.S. Code of Federal Regulations* (CFR) requirements by providing "sufficient information that the facility meets biosafety level requirements for working with the particular biological agent"

(42 CFR 72). The CDC is the supporting governmental agency under the HHS responsible for the management of the Laboratory Registration/Select Agent Transfer (LR/SAT) Program and would be the main point of contact for LLNL's Facility Responsible Official. LLNL would be required in accordance with the Integrated Safety Management System (ISMS) to participate in and follow the requirements of the CDC LR/SAT Program for handling of select agents[14] and must follow the provisions that apply to the six LR/SAT components as appropriate, which include (1) the list of approximately 40 "select agents" that are "viruses, bacteria, rickettsia, fungi, and toxins whose transfer in the U.S. is controlled due to their capacity for causing substantial harm to human health;" (2) registration of the facilities; (3) filing of approved transfer form; (4) verification using audits, quality control, and accountability mechanisms; (5) agent disposal requirements; and (6) research and clinical exemptions (42 CFR 72). No select agents would be handled in the proposed BSL-3 laboratories without first obtaining IBC approval in accordance with ISMS and secondly prior registration and approval from CDC. Microorganisms that are not select agents would also be used in the BSL-3 laboratories but would still be handled according to CDC and NIH guidances and requirements. Operation of the proposed facility would also involve handling of microorganisms that are regulated by the U.S. Department of Agriculture (USDA) and require BSL-3 containment.

Microorganisms expected to be cultured (i.e., viable organisms) at the BSL-3 facility in the near term would be, but not limited to, the select agents *Bacillus anthracis*, *Yersinia pestis*, *Clostridium botulinum*, *Coccidioides immitis, Brucella spp., Francisella tularensis, and Rickettsia spp.* (see Appendix A). The facility may be used to handle small amounts of biotoxins which are generally handled at the biosafety level established for the microorganisms that produce them. The CDC and NIH guidances and requirements also extend to handling genetically modified microorganisms. All research in microbiology laboratories that involves altering microbial genomes follows standard procedures approved by NIH (NIH 2001). It is possible that the facility would receive genetically altered microorganisms. Before any infectious microorganisms would be handled in the BSL-3 laboratories, the IBC and the researcher, in accordance with CDC guidance, would perform a risk analysis. LLNL occupational medicine and the local medical community would be informed of the microorganisms to be handled in the BSL-3 laboratories and would be aware of the methods of identification and control of associated diseases.

All work with infectious microorganisms in the proposed facility must be approved and authorized by LLNL management in strict accordance with the following:

- Biological Weapons Convention Treaty (BWC 1972) permits defensive research for the purpose of developing vaccines and protective equipment.
- Appendix G of the UC Contract with DOE specifies, among other things, Work Smart Standards, which include adopted standards from CDC (42 CFR 73), NIH (2001), and the U.S. Occupational Safety and Health Administration (OSHA) (29 CFR 1910, 29 CFR 1926).

[14] Select agents are biological agents of human disease whose transfer or receipt requires a facility to be registered with the CDC under 42 CFR Part 72.6; select agents have historically been associated with weaponizing efforts.

- The LLNL Biosafety Operations Committee (LBOC), a diversified group of LLNL operational-level researchers and representatives from all LLNL-affected institutional and regulatory compliance organizations who are responsible for the first-level reviews of projects/microorganisms and provide recommendations to the IBC.
- The LLNL Institutional Biosafety Committee (IBC) who reviews and approves each project such as those involving recombinant DNA or pathogenic organisms and toxins before such work can be undertaken at LLNL.
- When completed,[15] LLNL safety and security documentation (Facility Safety Basis, Facility Safety Plans, Hazard Control Plans, Human Pathogens Exposure Program, and security assessments) would provide the key documentation framework for operation of the BSL-3 facility.
- The BSL-3 facility would undergo a readiness review prior to startup to ensure that the infrastructure for safe operation is implemented and that the health and safety of workers, public, and the environment is protected.

Operation of the proposed BSL-3 facility would also be in compliance with a variety of state and Federal regulations. For example, these regulations would include those promulgated by the U.S. Department of Agriculture (7 CFR 330, 9 CFR 92), U.S. Department of Commerce (15 CFR 730), OSHA (29 CFR 1910.1030), U.S. Postal Service (USPS) (39 CFR 111), U.S. Department of Transportation (DOT) (49 CFR 171-178), and the HHS (42 CFR 73). NNSA, LLNL, and currently applicable BMBL requirements (according to Work Smart Standards) would be certified as having been met before operations would begin at the proposed BSL-3 facility. Other non-governmental organizations that provide guidance for transportation of infectious agents include the *Dangerous Goods Regulations,* the *Infectious Substances Shipping Guidelines* of the International Air Transport Association (IATA 2006), and the *Guidelines for Safe Transport of Infectious Substances and Diagnostic Specimens* of the World Health Organization (WHO) (WHO 1997).

Appropriate PPE used by employees entering the laboratories would include eye protection, gloves (in some cases the worker would be double-gloved), and disposable closed-front gown or clothing (including disposable booties and disposable cap). Air-purifying respirators might be worn as an additional safety measure for some tasks. Workers' hands would be washed with disinfectant immediately before and after putting gloves on or after any potential contamination with infectious agents. Workers could shower after finishing their laboratory work upon removal of their PPE clothing if deemed necessary. Worker's hair would be kept short or secured away from the face and no skin would be exposed below the neck; workers would be required to wear socks, closed shoes, and long pants underneath the disposable coverings. The majority of all materials used in the BSL-3 facility would be disposable, but some reusable laboratory apparatus, such as test tubes or culture dishes may be needed for some minor amount of sterile work. No open flames would be allowed within the BSCs. Work in the three laboratories would be scheduled and planned to avoid conflicts within the laboratory areas. All workers in the BSL-

[15] Safety and security documentation, as well as facility specific protocols, are not completed until after decisions have been made to construct and operate buildings and detailed building designs have been completed. Therefore, these are future documents that would be completed for the BSL-3 facility if NNSA decides to proceed with its construction and operation.

3 laboratory areas would be informed of what other workers would be handling so that appropriate staging of work could occur. Open cultures would only be handled in BSCs. BSCs would be at negative pressure with respect to the room and the rest of the building. Airflow would always be directed away from the worker and into the BSC. Workers would be offered appropriate immunizations for the microorganisms being handled. They would also be tested for normal immunocompetancy[16], and would have medical treatment readily available in the event of an accidental exposure.

No radiological material would be used or stored in the BSL-3 facility. A pest program would be in place to control vector populations.

One of the three BSL-3 laboratories would have rodent handling capability (<100 rodents). The rodents (mice, rats, and possibly guinea pigs) would be in the BSL-3 facility only when part of a research study. These rodents would be cared for in accordance with federal regulations and guidelines. LLNL adopted the requirements of the Animal Welfare Act of 1968 (7 USC 2131-2157, as amended) and voluntarily adheres to the guidelines for the use of vertebrate animals in research established by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. These requirements are administered by the LLNL Associate Director for the BBRP and are implemented by the LLNL Institutional Animal Care and Use Committee (IACUC).

Rodents would be held in quarantine in another Building 360 Complex laboratory for at least 30 days prior to use in a BSL-3 laboratory. They would be maintained in enclosed cages that would individually be connected to the building exhaust air duct. All rodent studies would occur only in the BSL-3 BSCs. Rodents are routinely transferred from dirty to clean cages in the BSCs. Used cages would be closed, autoclaved without dumping the litter, then further cleaned and disinfected prior to reuse. Rodent studies could involve intravenous injections and therefore the laboratories would have sharps, sharps containers, and a "needlestick" program that would be developed at the outset and would focus on ensuring workers do not accidentally inject themselves (autoinjection). All rodents brought into the proposed facility would be euthanized for the purpose of post-mortem medical examination (necropsy). All necropsied rodents and rodent tissues would be sterilized in a tissue digester located in the rodent BSL-3 laboratory.

The BSL-3 facility would not be a large-scale research or production facility, which is defined as working with greater than 10 liters of culture quantities (NIH 2001). Quantities of each cultured microorganism would be further limited by experiment-specific procedures under IBC approval. Less than 1 liter of cultured microorganisms in their stationary growth phase (maximum cell density of about 10^8 cells per ml) would be the maximum quantity handled in any BSL laboratory at any point in time. This 1-liter quantity would only be removed from the BSC in 250 ml double-contained plastic containers with safety-caps. No open cultures (where the free liquid surface is exposed directly to the ambient air) would be allowed outside of the BSC.

Seed cultures or samples would be provided by commercial suppliers, research collaborators, or other parties associated with the LLNL projects. These may contain either previously identified or unidentified organisms. Identification provides diagnostic, reference, or verification of

[16] Immunocompetancy is the ability to have normal immunity from infection.

strains[17] of microorganisms present. Diagnostic and reference strains, which may include the geographic source of the sample, contribute to the understanding of the microorganism's original source and ability to cause disease. Rapid, accurate reference or verification of strains improves containment of infection through early and effective medical intervention, potentially limiting the progress of illness for those exposed to pathogens, determination of antibiotic resistance, and contamination or infection of others.

The CDC would periodically inspect the facility over the life-time of its operation. The inspections would be performed by CDC staff or its contractors.

Sample Arrival at the LLNL BSL-3 Facility for Processing: Sample shipments would only be received at the BSL-3 facility operating within the parameters specified in all established guidelines and requirements. If the samples would be select agents, they would only be accepted when the CDC Form 2 has been completed per regulations, the registration verified, and the requesting facility responsible official notified in advance of shipment according to CDC registration requirements. Biological materials or infectious agents could only be shipped to LLNL by commercial package delivery services, the U.S. Postal Service (USPS), other authorized entity, or delivered to the receiving area from an origination point within LLNL by a designated LLNL employee acting as a courier (39 CFR 111; 42 CFR 72; 49 CFR 171-178). Generally, shipment sample sizes would be small; a typical sample would consist of about a milliliter of culture media (agar solid) with live cells (a milliliter is about equal to one-fifth of a teaspoon in volume). Smaller samples could be shipped that would be microliters in size; the maximum probable sample size would be 15 milliliters.

The protocol for receiving and handling of samples (such as soil) would be worked out prior to receipt and reviewed and approved by the IBC. Receipt of the select agents must be acknowledged electronically by the requesting facility responsible official within 36 hours of receipt and a paper copy or facsimile transmission of receipt must be provided to the transferor within 3 business days of receipt. Upon this acknowledgement, the transferor would be required to provide to the LLNL-requesting-facility responsible official a completed paper or facsimile transmission copy of the CDC form within 24 hours to the registering entity (holding that facility's registration), in accordance with §72.6(c)(2) (42 CFR 72) for filing in a centralized repository.

All incoming packages (regardless of origination point) containing infectious agents would have to have been packaged in DOT-approved packages (42 CFR 72) (see Figure 2-6). These packages would be about 6 to 8 inches (15 to 20 cm) in height and about 3-4 inches (8 to 10 cm) in cylinder diameter. All shipping containers would be made of plastic and the samples would be double- or triple-contained. Transportation and interstate shipment of biomedical materials and import of select agents would be subject to the requirements of the U.S. Public Health Service Foreign Quarantine (42 CFR 71), the Public Health Service, and DOT regulations. Additionally, the U.S. Department of Agriculture regulates the importation and interstate shipment of animal or plant pathogens (7 CFR 330 and 9 CFR 92). Strict chain-of-custody procedures for samples arriving at the LLNL receiving site would be followed.

[17] Strains are the very lowest taxonomic (naming organisms) designation; it generally means cells descended from a single isolate which have not mutated significantly from the exact DNA sequence of that original single cell.

Biological shipments to and from LLNL could initially be as much as ten times the current levels (4 in and 2 out per month now) of shipments to existing LLNL biological research laboratories. Once the facility became fully operational and "stocks" of needed materials were established, the level of shipments would remain above current levels for these types of shipments but decrease from start-up levels. Due to the perishable nature of the samples at the BSL-3 facility, receiving and shipping of samples normally would only occur during weekday daylight hours and samples must be opened and used or restored (put in growth media) within 8 hours of arrival. External packaging material from packages received at the facility would be inspected, removed, auto-claved, and disposed of according to LLNL waste handling procedures. The biological material samples and their packaging would be left intact and in accordance with the established chain-of-custody record. The packages would be placed in safe and secure condition within the respective BSL-3 laboratory where workers would process them. Shipment of samples from the BSL-3

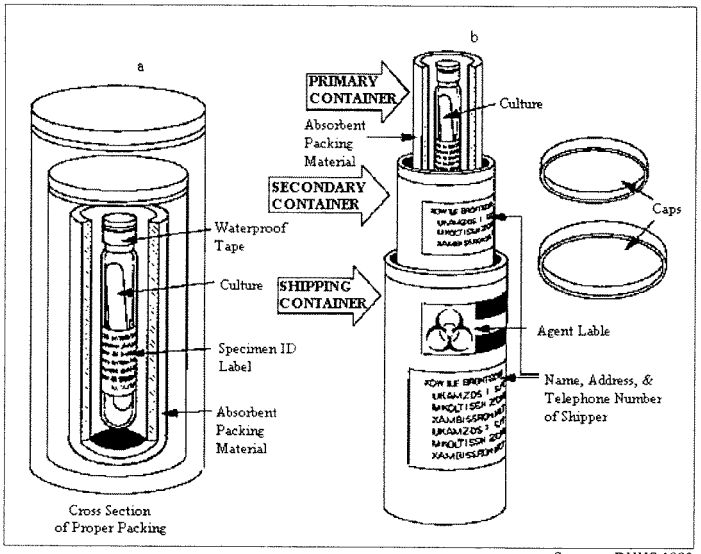


Figure 2-6. Example of a Primary Shipping Package.

facility to other researchers or the CDC would require following the same guidelines and requirements for the sample shipment that applied to samples received at the facility.

The samples may arrive at LLNL Shipping and Receiving in various fresh, frozen, or "fixed" (for example, in formaldehyde) forms including aqueous liquids, solids, or as material contained in bodily fluids. Samples would normally only contain vegetative forms (active growing stage) of microorganisms, but some spores could be present in samples. Other samples may contain proteins, DNA, or attenuated microorganisms (organisms that have been partially inactivated).

Upon arrival at LLNL Shipping and Receiving, these sample containers would be examined for damage, logged in, and taken to the BSL-3 laboratory for removal of the external packaging material. Damaged packages would be handled in accordance with procedures for BSL-3 laboratories (to be developed once the project obtains approval). The removed packaging would then be autoclaved and disposed as solid waste. The interior packing with the intact sample

would be placed safely and securely in the respective BSL-3 laboratory under chain-of-custody procedure until the authorized researcher is ready to process the samples. Unpacking any select agent primary container would only be done in the BSC. The samples would be stored in the BSL-3 laboratory within a locked freezer or refrigerator, according to the needs of the sample for preservation. Inventories of all samples and cultures would be kept. Samples and cultures would be identified by a numeric or alpha-numeric code rather than by the name of the microorganism or source. Sensitive information about samples and results would be maintained elsewhere at LLNL in a safe and secure manner in accordance with applicable NNSA and LLNL security requirements. The samples could also be immediately processed, in which case the materials would be placed directly into culture media (such as a liquid or semi-solid nutrient material or media). All preparations and manipulations of cultures or samples would only occur within a fully operating BSC. When the external packaging materials were removed, they would be autoclaved within the facility and disposed of according to LLNL's solid waste handling procedures (LLNL 1994).

Culture of Samples in a BSL-3 Laboratory: For culturing, the samples or seed cultures would be removed from their primary containers in a BSC, and a tube, flask, or plate containing a specific nutrient media would be innoculated with the sample to create a culture. All culture work would be completed and cleaned up within one work-shift (8 hours) except for materials being incubated. Culture and culture-storage containers would typically be made of plastic and always be double-contained. The culture container would be transferred to a temperature-controlled incubation chamber to grow the organisms (multiply the number of microorganisms) for a period lasting up to several days. Centrifugation of live, intact microorganisms would be conducted in sealed containers placed inside sealed tubes to minimize the potential for aerosolization[18] of microbes, or, if appropriate, centrifugation could be conducted inside a BSC. Cultured materials, which are sources for research materials, could be "lysed" (broken open) or killed (inactivated) by the addition of a variety of chemicals such as detergents or the chemical known as phenol. The lysed or killed cells and the culture media could be processed into biological material that would later be analyzed by various research methods at various LLNL research laboratories, and potentially at other laboratories off-site. Following incubation (hours to days), all cultured materials would be cleaned up within one work-shift (8 hours). Many cultures would be archived in small quantity and maintained in the ultra-freezers in each laboratory.

Waste Generation at the BSL-3 Facility: It is expected that little soil and construction debris would be generated from site preparation and construction activities of the proposed BSL-3 facility that would require disposal and removal from the construction site. Sanitary waste from portable toilets used during construction would be removed by commercial vendors and be disposed of in a sanitary sewer system offsite from LLNL in accordance with the permit requirements applicable to the commercial vendors.

During operation of the BSL-3 laboratories, the disinfection after each use of the interior working surfaces of the BSCs would generate waste products. All wastes generated in the laboratories of the facility (including sample packaging materials, culture materials, petri dishes,

[18] Aerosolization is the process of converting a liquid into droplets that are small enough to become dispersed in the air. In this case the droplets may contain one or more microbes.

PPE, and associated process wastes) would leave the laboratories only after decontamination using the facility's autoclave or after being chemically sterilized. The autoclaving process involves placing waste to be autoclaved in a special container. When autoclaving occurs, an indicator strip on the container changes color. This allows facility workers and waste management workers to be able to tell at a glance whether waste has undergone autoclaving. Performance of the autoclave is automatically tracked electronically to insure its effectiveness. This method is the same waste management method used by hospitals and similar facilities to sterilize their waste. Solid waste landfills may accept autoclaved or chemically sterilized wastes for disposal depending on their individual waste acceptance criteria and operating permit requirements. Alternatively, LLNL could contract to send sterilized wastes produced by the proposed BSL-3 facility to a licensed commercial incinerator located offsite for waste disposal.

Laboratory research experiments would be expected to generate about 22 lbs (9.9 kg) of lab trash (gloves, pipette tips, culture tubes, tissues, etc.) per week or about 1,144 lbs per yr (515 kg per yr). Other "solid waste" (note-paper, etc.) generated in the non-laboratory portions of the facility would raise the total solid waste production to less than 2,000 lbs per yr (900 kg per yr).

Sanitary liquid waste also would be generated from the proposed BSL-3 facility. Sanitary waste would be generated from research activities and from toilets, showers, and sinks in the building bathroom facilities. Sinks in each of the three laboratories would also generate sanitary waste. Soluble or liquid waste materials generated from laboratory operations can be disposed in the laboratory sinks after first being treated by autoclaving or with disinfectants. Other non-sewerable liquid wastes will be treated with disinfectants and removed by waste technicians. Waste generated from research is projected to be about 3 gal per wk (11 liters per wk) or 156 gal per yr (590 liters per yr), and could be disposed in the sanitary sewer system. An additional 40 gal per day (152 liters per day) or 10,000 gal per yr (37,900 liters per yr) can be produced by toilets and showers, although it shouldn't be considered a net increase since the BSL-3 facility workers are already working in adjacent BSL-2 buildings with toilets and showers.

Minimal amounts of hazardous waste (less than 2 gallons per year) and no radiological waste would be generated by the facility.

Chemical disinfectants would be used to disinfect portions of the laboratories that are not readily accessible, such as the ductwork. These disinfectants would be in a gas form as appropriate for the respective chemical. The space to be disinfected would be sealed, personnel would be excluded, and the gas would remain in the space for several hours before release to the environment. This procedure would be conducted by a certified technician using a standard protocol. The quantities of chemicals used would be well below the reportable quantities for both the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 300) and the Emergency Planning and Community Right-to-Know Act (EPCRA) (40 CFR 350). For example, if paraformaldehyde is used, the CERCLA-reportable quantity is 1000 lb. and for the vapor phase produced, formaldehyde, it is 100 lb. The EPCRA-reportable threshold for formaldehyde is 10,000 lb. Formaldehyde is also listed as a Hazardous Air Pollutant (HAP) under the Clean Air Act Amendments. HAPs are limited to 10 tons per yr individually.

All hazardous chemicals used in the proposed facility (such as: formaldehyde, chloroform, phenol, ethyl alcohol, isopropyl alcohol, amyl alcohol, and sodium hypochlorite) would not become waste for this facility. Only small quantities of these chemicals (sufficient for daily activities) would be present in the facility at any time due to a lack of storage space in the facility. These chemicals would either be used up in process (becoming non-hazardous) or would leave the facility as a stabilizing or sterilizing chemical for samples being sent to other laboratories. About 30 lbs per month (14 kg per month) or 360 lbs per yr (168 kg per yr) of sodium hydroxide or potassium hydroxide would also be used for rodent tissue digestion/sterilization. These chemicals would be used up in the digestion process. Waste fluid generation may need pH adjustment prior to discharge to the sanitary sewer system if it is too alkaline to meet discharge standards.

For any chemical disinfectant used by the BSL-3 facility, quantities used annually would not exceed reportable quantity volumes. Decontamination of the facility would include the use of chemical disinfectants, as discussed in the previous paragraph. This would allow the facility to be decontaminated, decommissioned, and demolished using standard construction practices. The resulting waste could be disposed of at a local landfill.

2.1.3 BSL-3 Facility Decontamination and Decommissioning

It is estimated that the operational design life of the proposed building would be at least 30 years. Decontamination and either demolition, removal, or reuse of the facility would likely occur. After decontamination (which would include disinfection of certain parts of the facility) the building could be disassembled and disposed of through the existing LLNL program for disposition of excess government property. This could ultimately require that the facility's modular components be moved offsite from LLNL. Alternately, the facility could be demolished and disposed of in a solid waste landfill offsite. Another alternative would be the reuse of the facility, either in whole or in part by other LLNL users, since BSL-2 laboratory space is traditionally in short supply at LLNL. Additional NEPA compliance review would be required when the decontamination and future-use options were ripe for review/decision.

The ultimate decontamination and decommissioning (D&D) of the BSL-3 facility would involve only the normal deconstruction and disposal of construction debris. This facility would undergo a final fumigation and testing to insure that microbes were not lingering in the remnants of the building. The building would not contain any radioactive or hazardous components.

2.2 Alternative Action to Remodel/Upgrade a Single-Room Laboratory in Building B-365 to BSL-3

It is expected that the cost of upgrading an old facility, such as a laboratory room in LLNL building B-365 (Figure 2-1) would approach or exceed the cost of constructing a new facility with the same single-laboratory capabilities. The initial problem of upgrading is the need for physical isolation of the laboratory space. Since the facility was not originally intended for this purpose it would not lend itself directly to physical isolation. The most significant retrofits in terms of cost and time would involve HVAC systems; HEPA filtration' fumigation systems; and sealing of walls, floors, ceilings, plumbing and electrical conduits. Often a new room inside the

room must be installed to insure complete sealing of entrance/exit points around all the normal breaches, such as wall electrical outlets. The "remodel" option also often has problems; for example, with: sanitary sewer drainage (where this lab is located relative to others in the same building); HVAC pressure balancing (effects from other room doors opening/closing and BSCs); addition of HEPA filter banks for disinfection without shutdown of system; and location of exhaust stacks relative to other existing intakes.

This option is not necessarily a cost-effective one, but it can and has been done by the CDC in Atlanta, GA. Discussion with personnel from the CDC (PC 2001a, 2001b) suggest that their biggest problems come from retrofit laboratories. The CDC personnel would not recommend this alternative.

2.3 ALTERNATIVE ACTION TO CONSTRUCT AND OPERATE AN ON-SITE-CONSTRUCTED BSL-3 FACILITY

An alternative to a modular construction would be on-site construction. The only appreciable difference in the installation of a modular assembly constructed off-site and the on-site construction option is the duration of the construction phase and the associated noise, traffic, and movement of building materials. The installation of a modular assembly on-site takes a matter of weeks while the on-site construction takes months and is more disruptive for a longer period. Once constructed, there is no appreciable operational difference between them. The operational and D&D phases would, for all intents and purposes, be the same as for the proposed action.

2.4 NO ACTION ALTERNATIVE

The No Action Alternative provides a description of what would occur if the Proposed Action were not implemented to compare with the potential effects of the Proposed Action. This alternative must be considered even when the Proposed Action is specifically required by legislation or court order (10 CFR 1021.321[c]). Under the No Action Alternative, NNSA would not construct or operate the BSL-3 facility. In this event, NNSA would have to continue to rely on meeting its BSL-3 laboratory needs by exporting work and staff to existing or new BSL-3 laboratories located offsite from LLNL. It is expected that while the potential tasking of LLNL by DOE and through work-for-others would grow, no new workers would be hired within the BBRP at LLNL since the only need to hire additional staff under this option would be to be able to export staff and equipment to offsite laboratories as workloads increase rather than to conduct the research on-site with currently existing staff assets which should remain sufficient for the foreseeable future. Also, there would continue to be certain NNSA national security mission needs that could not be met in a timely fashion, or that may not be able to be met at all. The No Action Alternative would not meet NNSA's identified purpose and need for action at LLNL.

2.5 ALTERNATIVES CONSIDERED BUT ELIMINATED FROM FURTHER ANALYSIS

Additional alternatives were considered but have been dismissed from detailed analysis in this document.

2.5.1 Construction and Operation of the Proposed BSL-3 Facility at Another Mainsite LLNL Location

The LLNL mainsite is very space-limited. There are few remaining open areas available for new construction, and none in the near vicinity of the BBRP complex. However, any location other than the proposed location would be, at a minimum, a logistical problem. First, it is expected that the researchers and staff who would be working in the proposed BSL-3 facility would have offices and regular work assignments in buildings adjacent to the proposed facility location in the Building 360 Complex under the preferred alternative. This is also where the rodent colony and quarantine areas are located, as are all the supplies for the proposed building. From a safety perspective, the LLNL Biosafety Officer and the most highly trained and experienced staff would also be located in the buildings immediately adjacent to the currently proposed building location. A remote location would be a safety and security risk that is unnecessary. This alternative was dismissed from further consideration in this NEPA analysis although it would meet the Agency's purpose and need for action.

2.5.2 Construction and Operation of the Proposed BSL-3 Facility at Site 300

The same issues apply to Site 300 as they do for another mainsite LLNL location (section 2.5.1), although the significance of the safety issues and issues related to ground transport of infectious agents and toxins between the two sites are greater. This alternative also was dismissed from further consideration in this NEPA analysis although it would meet the Agency's purpose and need for action.

2.5.3 Construction and Operation of the BSL-3 Facility at Another National Security Laboratory

The NNSA supports three national security laboratories: Los Alamos National Laboratory, at Los Alamos, New Mexico, the Sandia National Laboratories at Albuquerque, New Mexico (SNL/NM) and Livermore, California (SNL/CA), and Lawrence Livermore National Laboratory (LLNL), at Livermore, California. Construction and operation of the proposed BSL-3 facility at either SNL or LANL to the exclusion of LLNL was considered, as it is possible to construct such a facility at any of the national security laboratories at approximately the same cost and schedule. This alternative would not, however, meet the purpose and need for NNSA to conduct future BSL-3 level work at LLNL in support of its assigned national NNSA security –and science mission responsibilities.

This alternative would almost be the same as the No Action Alternative with the exception being that work could be done under more precise quality assurance procedures and under conditions that would meet the necessary national security requirements needed. However, it would not allow the work to be performed as quickly or efficiently as may be needed in all cases. LLNL has qualified and experienced personnel and a sophisticated existing biological infrastructure in the BBRP. Placing the BSL-3 laboratory at another NNSA laboratory would require significant duplication of this capability. Also, none of the existing or proposed (DOE 2002b) NNSA locations, which are all now operating at the BSL-2 level, have or would have the capability to conduct aerosol challenges of rodents.

Work at each of the national laboratories is expected to complement rather than be duplicated at each of three national laboratories. While these other facilities may consider the construction and operation of a BSL-3 facility in the future, the operation of these laboratories would be directed toward meeting their individual mission work requirements and would not be identical to that performed by the other laboratories in the NNSA complex. Therefore, the alternative to constructing a BSL-3 facility at either of two other national security laboratories is not considered further in this EA analysis as it does not meet NNSA's purpose and need for agency action at LLNL.

2.6 RELATED ACTIONS

There are no known related actions.

3.0 AFFECTED ENVIRONMENT

The *Final Environmental Impact Statement and Environmental Impact Report for the Continued Operation of Lawrence Livermore and Sandia National Laboratories, Livermore, August 1992* (LLNL FEIS/EIR) (DOE 1992) and its associated Supplement Analysis (SA) (DOE 1999) provided a detailed discussion of the affected environment baseline for the original version of this EA. In 2005, DOE issued the *Final Site-wide Environmental Impact Statement for Continued Operation of Lawrence Livermore National Laboratory and Supplemental Stockpile Stewardship and Management Programmatic Environmental Impact Statement* (SWEIS, DOE/EIS-0348, DOE/EIS-0236-S3, DOE 2005). Background information in this version of the EA has been updated to reflect information in the SWEIS if the updated information is pertinent to NNSA evaluation of the effects of the proposed action on human health or the environment.

This section describes the environmental resources that may be affected as a result of implementing the Proposed Action to construct and operate a BSL-3 facility. Resources are described using the sliding scale approach with more detail provided for resources that might be most affected. Resources are either addressed in this section or eliminated from detailed discussion, as shown in Table 3-1 in Section 3.2.

3.1 REGIONAL AND LOCAL SETTING

The LLNL Livermore site occupies a total area of approximately 3.3 km^2 (821 acres) at the southeast end of the Livermore Valley, located about 80 km (50 miles) east of San Francisco, in southern Alameda County, California. The Livermore Valley is characterized by nearly level, shallow-to-deep soils that vary in texture from clays to sandy clay loams or mixed gravels. The valley forms an irregularly shaped lowland area about 16 miles long east-to-west and 7 to 10 miles wide north-to-south. The floor of the valley slopes to the west at about 20 ft per mi (4 m per km). The soils tend to be high in sodium, calcium, magnesium, iron, chlorides, and sulfur, and low in organic matter, nitrates, phosphates, and potassium. The characteristics of the soil series found at the Livermore site are hard when dry and plastic when wet; the soils have high permeability and high water-retention capacity. Since the Livermore site is nearly flat, there would be no areas of potential slope instability in the location of the proposed project.

3.1.1 Climate and Meteorology

The Livermore Valley is characterized by mild, rainy winters and warm, dry summers. The mean annual temperature for the 30-yr period from 1950 through 1980 is 14.5°C (58.1°F) with daily extremes ranging from -8°C (18°F) to 45°C (113° F).

Both rainfall and wind exhibit strong seasonal patterns. Most of the annual rainfall, which averages 36 cm (14 in.), occurs between October and April and is associated with migratory, low-pressure systems from the Gulf of Alaska. Prevailing winds are from the west and southwest from April through September. During the wet season, northeasterly and north-northeasterly winds that are associated with post-frontal, anti-cyclonic flow are also common. Figures 3-1 and

3-2 show the day and nightime wind roses for LLNL for the five-year period from January 1997 through January 2002.

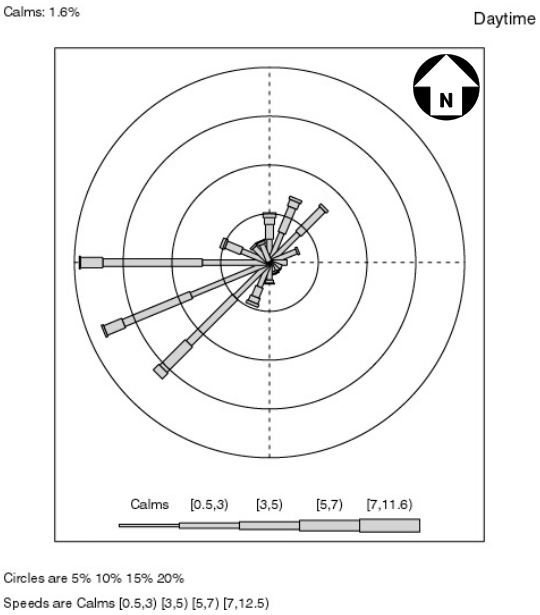


Figure 3-1. 5-Yr daytime wind rose for LLNL

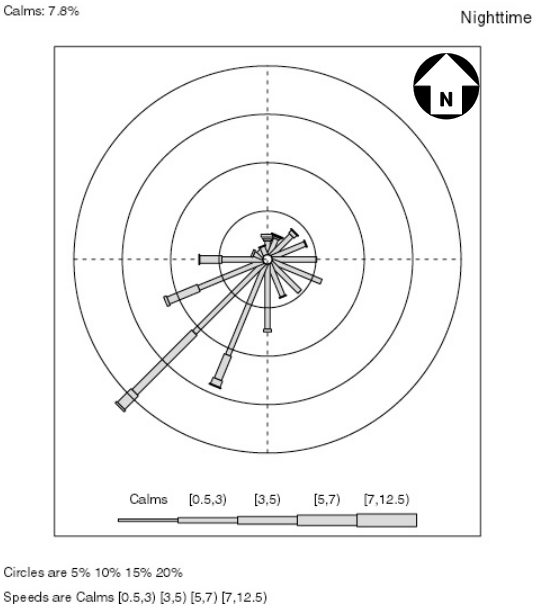


Figure 3-2. 5-Yr nighttime wind rose for LLNL

3.2 ENVIRONMENTAL RESOURCES NOT AFFECTED

Discussion of the Affected Environment is limited to existing environmental information that directly relates to the scope of the Proposed Action and the alternatives analyzed. Table 3-1 shows the resource categories and whether they are applicable or not (EA section is not applicable, NA, and a brief explanation of why not) and where they are discussed if they have a direct bearing on the analysis.

Table 3-1. Applicability of Resource Categories to the BSL-3 Analysis

Resource Category	Applicability	BSL-3 EA Section
Ecological Resources	Yes	3.3.1
Human Health	Yes	3.3.2
Air Quality	Yes	3.3.3
Noise	Yes	3.3.4
Waste Management	Yes	3.3.5
Geology/Soils/Seismology	Yes	3.3.6
Socioeconomics	The projected financial expenditures for the proposed construction project would be too small to have any perceptible affect on the local environment. No net increase in the number of workers would be anticipated.	NA
Visual Resources	This facility would be consistent in architectural style with, and in the midst of, a number of larger buildings. No visual issues would be perceived.	NA
Transportation	The number of LLNL material shipments associated with operating the proposed facility would be imperceptible to LLNL and there would be no net change in the number of individuals working in the Building 360 Complex area.	NA
Utilities/Infrastructure	The small size of the proposed facility and its intended location show that there would be no appreciable impact to utilities and infrastructures.	NA
Cultural Resources	No prehistoric or historic cultural properties greater than 100 yrs old are located at or adjacent to this site (DOE 1992).	NA
Environmental Justice	There would be no disproportionately high or adverse human health or environmental effects on minority or low-income populations (DOE 1992) as a result of operating an on-site BSL-3 facility in addition to the current BSL-2 facilities.	NA
Environmental Restoration	There are no potential release sites at or adjacent to the proposed location (DOE 1992).	NA

Table 3-1. Applicability of Resource Categories to the BSL-3 Analysis

Resource Category	Applicability	BSL-3 EA Section
Floodplains/Wetlands	The proposed facility is not within the 100-yr floodplain nor are there wetlands at or adjacent to it (DOE 1992).	NA
Land Use	The area surrounding the proposed site is made up of office buildings, laboratories, storage and warehouse facilities, and parking lots, all illuminated at night. The proposed construction and operation of a BSL-3 facility would not alter the character of the site areas or introduce new land use elements (DOE 1992).	NA
Water Quality/Hydrology	There would be no effect on surface water or groundwater quality and no perceptible increase in potable water use. There are no NPDES outfalls at the proposed facility location (DOE 1992).	NA

3.3 ENVIRONMENTAL RESOURCES POTENTIALLY AFFECTED

3.3.1 Ecological Resources

The Livermore site is a developed area that provides only marginal wildlife habitat because of the high degree of human activity and the few areas of undisturbed vegetation. Of the 3.3 km^2 (821 acres) comprising the Livermore site, 2.6 km^2 (640 acres) are developed. Annual wild oat along with non-grass annuals and perennials now dominate the grassy areas of the site. The common plant species are ripgut brome (*Bromus diandrus*), slender oat (*Avena barbata*), star thistle (*Centaurea solstitialis*), Russian thistle (*Salsola kali*), turkey mullein (*Eremocarpus setigerus*), alfalfa (*Medicago sativa*), sweet fennel (*Foeniculum vulgare*), California sagebrush (*Artemisia California*), and Italian ryegrass (*Lolium multiflorum*).

The LLNL Livermore site hosts numerous birds, reptiles, and amphibians, with a minimum of 3 species of amphibians and reptiles, 10 species of mammals, and 31 species of birds. Jackrabbits are the most common wild mammal present; gophers, snakes, and field mice can be found in the undeveloped areas of the Livermore site.

Resource surveys of LLNL Livermore, California, were conducted in 1986 (Orloff 1986), and a biological assessment (BA) in 1991 pursuant to the U.S. Endangered Species Act and the State of California Endangered Species Act addressed the status of threatened, endangered, and other species of concern (referred to as sensitive species) that may occur or are known to occur in these areas. Although several listed and proposed endangered and threatened species of plants and animals may occur in the general area of the LLNL Livermore site, the U.S. Fish and Wildlife Service (USFWS) determined that, to the best of its knowledge, these species were not known to occur within the boundaries and proposed future growth areas of these sites at that time (U.S. Fish and Wildlife Service 1991). Since that time, one State-protected bird species, the White-tailed kite (*Elanus leucurus*), has been found to nest along the eastern and northern tree line of the site, in spite of normal daily traffic and routine maintenance activities; also, one state species of special concern, the Burrowing Owl (*Athene cunicularia*), had been found in the north

buffer zone of the LLNL Livermore Site in the mid-1990s. Additionally, the Federally threatened California red-legged frog (*Rana aurora draytonii*) has been found in the Arroyo Los Positas (along the northern buffer zone). A BA was completed in 1997 and amended in 1998 to account for potential impacts to the frog from routine maintenance activities at the LLNL site. In 2001, a narrow strip along the northern and eastern edges of the site were designated as a portion of the federal critical habitat for the frog. The proposed BSL-3 facility would not be located in or near these natural resource-sensitive areas.

Although not usually considered as such, soils are also an ecological resource (Burden and Sims 1999). Soils are known to naturally contain a diversity of numbers and types of microorganisms. The range is substantial as it depends upon the environmental conditions, which dictate the bacteria and fungi microflora (plant microorganisms) that can survive. Infectious microorganisms can also be found naturally in soils. Some of these may be handled in the proposed BSL-3 laboratories (e.g., *Bacillus spp.* and *Clostridium spp.*).

3.3.2 Human Health

In 2000 there were approximately 1.3 million people living in Alameda County (HRSA 2000), in which Livermore is located, and about 6.9 million people living within a 50-mile radius of LLNL (LLNL 2001b). Health of individuals living here is favorable (better) relative to California peer counties and the U.S. as a whole (HRSA 2000). Infectious diseases are not common in the county. In fact, over the three year period of 1996, 1997, and 1998, most of the infectious diseases were diarrheal (63 cases from *Escherichia coli*, 809 cases from *Salmonella spp*. and 441 cases from *Shigella spp*.) associated with either unclean water or improper hygiene and food handling (HRSA 2000). There were also 472 cases of viral hepatitis A (infectious hepatitis), 21 cases of viral hepatitis B (serum hepatitis), 8 cases of the measles virus (Rubeola), and 109 cases of pertussis (whooping cough) reported to Alameda County Health officials (HRSA 2000).

Statewide there are appreciably more cases of infectious diseases. Table 3-2 shows the cases and deaths associated with selected notifiable diseases in the State of California for a four-year period (CDF 2001). These statistics show, for example, that while there were no cases of anthrax for the reported years, there were a few cases of plague (unspecified), psittacosis, Q-fever, brucellosis, tularemia, and typhus, along with a number of more common diseases. Although not on the table, there were 9 hantavirus cases in 1999. Acquired immune deficiency syndrome (AIDS) and venereal diseases are some of the most prevalent infectious diseases in California.

3.3.3 Air Quality

Air quality is a measure of the amount and distribution of potentially harmful pollutants in ambient air. Congress passed the *Clean Air Act* (CAA) to mandate that the U.S. Environmental Protection Agency (EPA) regulate those potentially harmful pollutants through the National Ambient Air Quality Standards (NAAQS) for pollutants of concern known as the criteria pollutants. EPA has identified six criteria pollutants: carbon monoxide (CO), sulfur dioxide (SO_2), nitrogen oxides (NO_x), ozone (O_3), lead (Pb), and particulate matter (PM). These pollutants are emitted primarily from combustion sources such as boilers, emergency generators, and motor vehicles. Criteria pollutant emissions data for LLNL have not changed appreciably

TABLE 3-2. CASES AND DEATHS, SELECTED NOTIFIABLE DISEASES CALIFORNIA, SELECTED YEARS

T.C.D. 10th Edition		1990		1997		1998		1999	
		Cases	Deaths a/	Cases	Deaths a/	Cases	Deaths a/	Cases	Deaths a/
B20-B24	AIDS	8,827	5,041	6,774	1,857	5,786	1,432	5,358	1,558
A06	Amoebiasis	1,638	2	933	1	700	1	599	---
A22	Anthrax	---	---	---	---	---	---	---	---
A05.1	Botulism	36	---	48	1	51	---	65	3
A23	Brucellosis	26	---	30	1	12	---	18	---
P01.9, P35.8 *	Chickenpox (Varicella-Zoster)	904	32	n/r	23	n/r	22	n/r	---
B38 *	Coccidioidomycosis	441	23	704	50	719	36	939	28
A93.2	Colorado Tick Fever	---	---	---	---	1	---	---	---
P39.1	Conjunctivitis of the Newborn	25	---	23	---	25	---	21	---
	Diarrhea of the Newborn h/	---	---	---	---	---	---	---	---
A36	Diphtheria	---	---	---	1	---	---	---	---
	Encephalitis, Viral	125	17	76	17	79	14	108	---
	Food & Waterborne Illness	1,079	---	1,951	2	3,968	1	3,617	---
P35.0	Rubella-Congenital	8	6	3	1	---	2	2	---
B15-B19 *	Hepatitis, Viral	10,594	265	8,658	704	6,210	860	4,961	248
B15	A (Infectious)	6,408	15	6,422	21	4,178	10	3,439	20
B16	B (Serum)	2,940	145	1,658	186	1,445	222	1,234	58
B17.1, B17.8 *	Non-A, Non-B b/	623	---	467	467	464	595	191	131
B17.0	D	8	105	8	30	6	33	10	---
B19	Unspecified	615	---	103	---	117	---	87	9
A30	Leprosy	79	---	40	1	38	---	36	---
A27	Leptospirosis	3	1	12	---	2	---	1	---
B50-B54	Malaria	328	---	406	---	217	---	218	---
B05	Measles: Indigenous	12,719	39	22	---	6	---	14	---
	Measles: Imported	91	---	8	---	4	---	4	---
A87 *	Meningitis, Viral	1,525	7	2,307	3	3,040	4	1,544	4
A39	Meningococcal Inf.: d/	426	---	402	41	319	28	304	30
A39.2-A39.4 *	Meningococcemia	---	46	156	21	132	12	125	13
A39.0 *	Meningitis	---	---	215	12	153	13	154	10
B26	Mumps	571	1	151	---	110	1	95	---
A37.0 *	Pertussis	467	---	483	---	1,085	---	1,144	---
A20	Plague	---	---	2	---	1	---	---	---
A80	Poliomyelitis	---	---	2	---	1	---	1	---
A70	Psittacosis	8	---	8	---	6	---	3	---
A78	Q Fever	2	1	9	---	4	---	3	---
A82	Rabies, Human	---	---	---	---	---	---	---	---
A68	Relapsing Fever	10	---	7	---	7	---	8	---
100-102 *	Rheumatic Fever	25	11	11	12	5	15	10	2
A77.0	Rocky Mt. Spotted Fever	1	---	2	---	1	---	1	---
A01.1-A01.4, A02 *	Salmonella	5,725	8	5,993	6	4,724	6	4,208	4
A03	Shigellosis	5,703	4	3,221	1	3,033	---	2,364	---
A49.1 *	Streptococcal Infections c/	6	2	---	45	---	46	1	12
A33-A35 *	Tetanus	7	2	11	1	8	---	16	1
B75	Trichinosis	1	---	1	---	3	---	2	---
A16-A19 *	Tuberculosis	4,889	211	4,043	194	3,857	165	3,608	139
A21	Tularemia	---	---	4	---	3	---	3	---
A01.0	Typhoid Fever	149	---	83	---	83	---	73	---
A75 *	Typhus Fever	3	---	16	---	12	---	11	---
A50-A64 *	Venereal Disease e/	137,544	10	90,507	5	98,954	6	106,575	5
A57	Chancroid	159	---	13	---	14	---	6	---
	Chlamydia trachomatis g/	66,213	---	68,599	---	76,401	---	85,022	---
A54 *	Gonococcal Infections	54,076	1	18,002	1	19,555	---	18,656	2

TABLE 3-2. CASES AND DEATHS, SELECTED NOTIFIABLE DISEASES CALIFORNIA, SELECTED YEARS

T.C.D. 10th Edition		1990		1997		1998		1999	
		Cases	Deaths a/	Cases	Deaths a/	Cases	Deaths a/	Cases	Deaths a/
A58	Granuloma Inguinale	7	---	n/r	---	n/r	---	n/r	---
A55	Lymphogranuloma venereum	24	---	n/r	---	n/r	---	n/r	---
A50-A53	Syphilis, Total f/	17,065	9	3,893	4	2,984	6	2,891	3
A51 *	Primary	2,220	---	165	1	123	---	105	---
	Secondary	2,274	---	221	---	202	---	179	---

* The Tenth Revision of the International Classification of Diseases (ICD-10) codes may not be comparable to the Ninth Revision (ICD-9) codes. Caution should be used when looking at the number of deaths by year.

a/ Deaths shown above may not agree with deaths shown in vital statistics tables because some diseases are not listed separately in the International Classification of Diseases List of Causes of Death on which the vital statistics tables are based, or because the definitions of some of the diseases used in the International List differ from the definitions used for morbidity purposes.

b/ Non-A, Non-B is a new category added in 1982 by the Center for Disease Control, Atlanta, Georgia.

c/ Respiratory infections not included after 1988. After May 1989, cases reported only in foodhandlers, dairy workers and outbreaks.

d/ Prior subcategories combined for reporting beginning with 1993.

e/ Does not include NGU or PID.

f/ Also includes congenital, early latent, late and late latent syphilis.

g/ Chlamydia became a reportable disease in mid-1989; 1990 is considered the first full report year.

h/ Outbreak related cases only.

n/r No longer reportable.

Source: Department of Health Services, http://www.dhs.cahwnet.gov/
Cases--Communicable Disease Control Division, Office of Statistics and Surveillance, (916) 323-9808
Deaths--Office of Vital Records and Statistics, Vital Statistics Section, (916) 445-6355

since the 1992 FEIS (DOE 1992) with the exception that the Laboratory now lies within a federal non-attainment area for ozone. None of the criteria pollutants emitted from LLNL, when combined with existing background pollutant levels, substantially contributes to existing or new degradations of air quality in the Bay Area.

3.3.4 Noise

Noise levels to protect worker hearing at LLNL are based on DOE orders (DOE 1984), OSHA regulations (29 CFR 1910.95), and recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH 2000). The standard unit used to report noise or sound pressure levels is the decibel (dB); the A-weighted frequency scale (dBA) is an expression of adjusted pressure levels by frequency that accounts for human perception of loudness. Noise levels that affect residential receptors are normally limited to the maximum of 65 dBA during daytime hours and 53 dBA during nighttime hours (between 9 p.m. and 7 a.m.). Activities that do not meet these noise standards normally require a city or county permit.

Noise levels at the proposed BSL-3 facility would be generated primarily by vehicle traffic and facility HVAC systems except during facility construction. Ambient noise measurements for typical lightly industrialized areas are around 50 dBA during morning and evening rush hours dropping a few dBA during nighttime hours. These levels are comparable to outside noise levels generated at urban centers during daytime hours and common indoor sounds such as the background noise in a large occupied conference room. Noise levels for heavy construction equipment can be more than 20 dBA higher than typical light industrialized areas depending upon the proximity to the source of the noise and the type of equipment being used.

3.3.5 Waste Management

LLNL has established procedures for compliance with all applicable laws and regulations for collecting, storing, processing, and disposing of sanitary liquid wastes, solid wastes and hazardous wastes at LLNL. The quantity of solid waste expected to be generated by construction activities, relative to LLNL-wide waste generation, is negligible and minimal hazardous waste generation (less than 2 gal per year) is projected; therefore, neither will be further evaluated.

Sanitary Liquid Waste. Sanitary liquid waste from LLNL is discharged by sewer to the City of Livermore Water Reclamation Plant (LWRP) in accordance with procedures specified in the LLNL ES&H Manual (LLNL 2001c). All discharges are continuously monitored with a radiation detector, an industrial pH probe, and an x-ray fluorescence unit for most regulated metals prior to discharge off-site. Discharges are regulated by the federal government under the Clean Water Act (also known as the Federal Water Pollution Control Act of 1972, 40 CFR 403). The State of California regulates these discharges under Title 22 of the California Code of Regulations, and the City of Livermore imposes restrictions under the LLNL Wastewater Discharge Permit which is issued under Livermore's municipal code. Discharge limits for non-radioactive parameters include 11 inorganic elements/constituents plus pH (acidity), total toxic organics, volatile halogenated solvents, total identifiable chlorinated hydrocarbons (pesticides), oil and grease, and polychlorinated biphenyls. Although no discharge limits currently exist for infectious materials which are commonly discharged by healthcare and veterinary facilities and laboratories or homes, liquid waste as generated from the proposed BSL-3 laboratory operations would be discharged to a retention tank system, for containment, characterization, and disinfection as needed, prior to discharge to the sanitary sewer system.

3.3.6 Geology/Soils/Seismology

The LLNL Site Seismic Safety Program recently performed a new analysis of the geologic hazards at the Livermore Site (LLNL 2002). Although new data and updated methodologies were used, the most recent study reports essentially the same results as previous studies for the prediction of the peak ground acceleration. The results of these seismic hazard analyses and the evaluation of structures are presented in the Sitewide Environmental Impact Statement for Continued Operations, Lawrence Livermore National Laboratory (DOE 2005).

The Livermore Site is located near the northwest-southeast trending boundary separating the North American and Pacific tectonic plates, or San Andreas Fault system (Figure 3.3). Regionally significant structures are associated with the San Andreas Fault system, including the Hayward and Calaveras faults east of the San Francisco Bay Area. The closest structure to the Livermore Site associated with the San Andreas Fault system, the Calaveras Fault, is situated approximately 15 miles west of the site. The San Andreas, Hayward, and Calaveras faults have produced the majority of significant historical earthquakes in the Bay Area, and accommodate the majority of slip along the Pacific North American plate boundary. These structures will likely continue generating moderate to large earthquakes more frequently than other faults in the region (LLNL 2002). Local structures include the Greenville, Mount Diablo, Las Positas, and Corral Hollow faults. Although the Greenville Fault outcrops are within 1 mile of the Livermore Site,

they have the lowest slip rate of any structures associated with the San Andreas system. The Mount Diablo Thrust Fault, postulated to underlie the Livermore and Sycamore Valleys on the basis of seismic reflection data, is related to the development of fold structures in the area. The Las Positas Fault passes 1 mile southeast of the Livermore Site and is considered capable of generating relatively infrequent moderate earthquakes. Additionally, the Corral Hollow Fault zone passes approximately 2 miles east of the site. In a recent study (LLNL 2002) assessing local seismic hazards, the existence and characteristics of the Verona, Williams, Livermore, and Springtown faults were considered.

A recent U.S. Geological Survey (USGS) study of the likelihood of major earthquakes in the San Francisco Bay Area determined that there is a 62 percent probability of one or more earthquakes with a magnitude of 6.7 on the Richter Scale or greater occurring within the next 30 years (USGS 2003). The study concluded that the probability of these earthquakes occurring along the Calaveras and Greenville faults, and the Mt. Diablo Thrust Fault within the next 30 years was 11 percent, 3 percent, and 3 percent, respectively. The study calculated that there was a 50-percent chance of the Livermore area exceeding a ground shaking of Modified Mercalli (MM) intensity VII to VIII. The Association of Bay Area Governments (ABAG) has mapped the distribution of ground-shaking intensity (Association of Bay Area Governments 2001). A large earthquake on the Greenville Fault is projected to produce the maximum ground-shaking intensities in the Livermore area with intensity ranging from strong (MM VII) to very violent (MM X). The MM IX level would result in damage to buried pipelines and partial collapse of poorly built structures (City of Livermore and LSA 2002).

Seismic hazard analyses have been performed for the Livermore Site to quantify the hazard. The analyses identify the probability of exceeding a given peak ground acceleration. The 2005 SWEIS describes the maximum horizontal peak ground accelerations at the Livermore Site for return periods of 500 and 1,000 years as 0.38 *g*, and 0.65 *g*, respectively. The technical basis for these peak acceleration values is provided in Appendix H of the 2005 Sitewide EIS (DOE 2005).

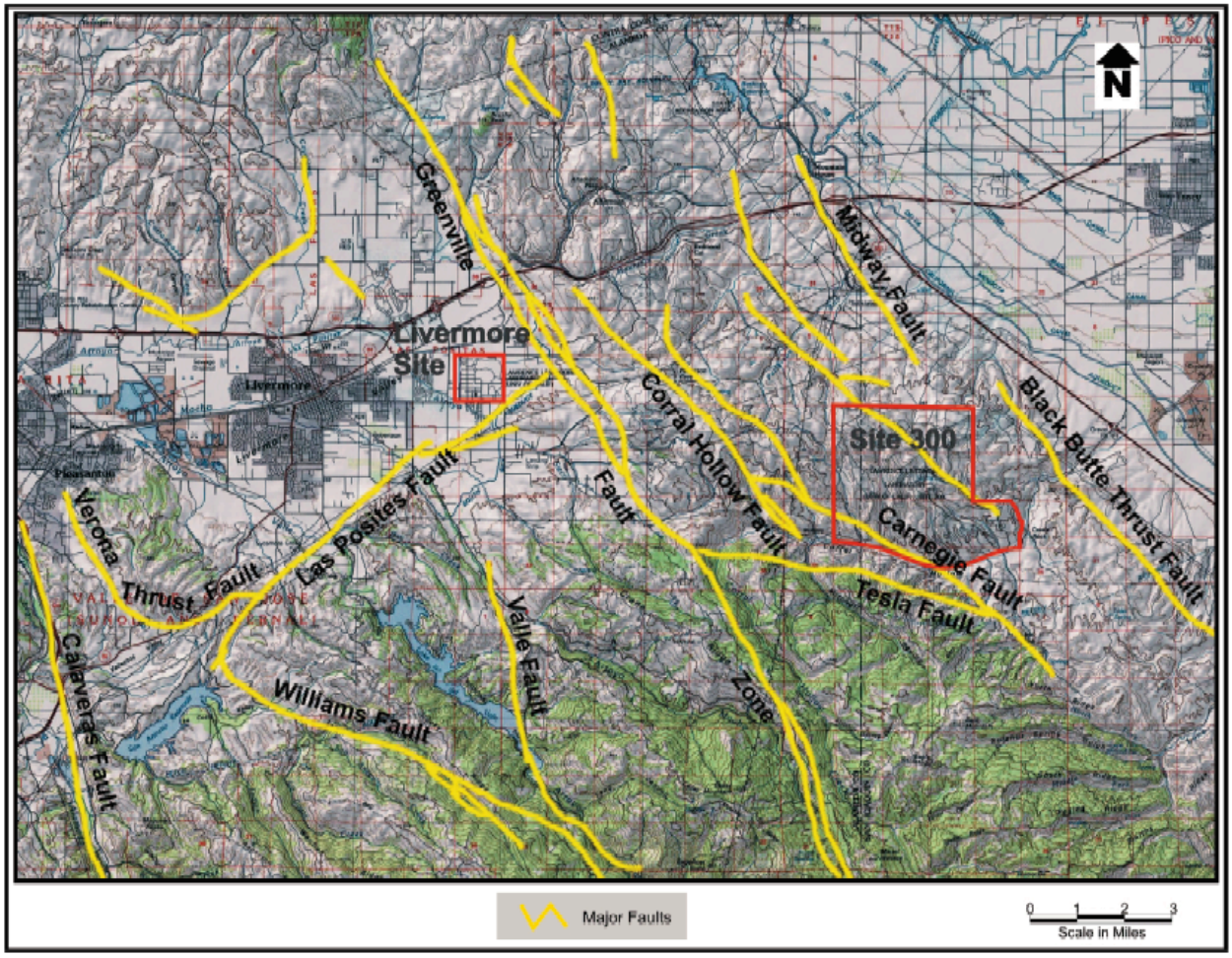


Figure 3-3. Map showing major faults in the Livermore region (DOE 2005)

4.0 ENVIRONMENTAL CONSEQUENCES

This section evaluates the environmental consequences of the Proposed Action, Alternative Actions and the No Action alternative. Except for the No Action Alternative, this evaluation covers site preparation, construction, operation, abnormal events (accidents or malicious acts), and decontamination and decommissioning. The consequences of the Proposed Action and the Alternative to Construct On-site would be the same except for those related to construction. The Remodel/Upgrade Alternative would have no site preparation, so the discussion covers construction, operation, and D&D. The abnormal event (accident or malicious act) issues are the same for all alternatives since the work in all alternatives would be done in an individual laboratory conforming to CDC/NIH guidelines for design and operation of a BSL-3 laboratory.

4.1 ENVIRONMENTAL CONSEQUENCES OF THE PROPOSED ACTION

4.1.1 Ecological Resources

As stated in Section 3.3.1, no threatened or endangered species habitat or buffer areas would be located at or adjacent to the proposed BSL-3 laboratory facility.

Site Preparation and Construction. Less than one-quarter acre of previously disturbed land would be used for site preparation, utility installation, and other construction activities. It would be expected that continuous and impact noise (described in Section 4.1.4) could have temporary effects to non-sensitive wildlife species in the immediate site location area. However, these minor effects would not be long term.

Site preparation and construction would have some effect upon the resulting soil characteristics. A small portion of some shallow soil horizons would be removed where they would be under foundation footings and other parts of the building's base. Soil microflora would be disturbed but only for the duration of soil-intrusive activity.

Operation. The operation of the proposed BSL-3 facility would have little if any effects on biota. Infectious microorganisms handled in the proposed facility might be introduced into the environment under two conditions. The first is the disposal of sanitary wastewater to the City of Livermore Water Reclamation Plant (LWRP) discussed previously. Sanitary waste passing through the wastewater treatment plant undergoes several stages of treatment that would inactivate any microbes that survived the initial disinfectant treatment at the BSL-3 facility (see discussion of water-borne transmission in Section 4.1.2, Human Health). This process is the same as for healthcare and veterinary facilities and laboratories in the area.

The second relates to emergency response operations. There is a potential for microorganisms to be introduced into the environment if they were not contained within the laboratory during a fire-response or natural phenomena event (e.g., seismic). However, even if they should escape containment, a number of environmental factors should effectively kill microorganisms in the vegetative state. These are enumerated in Section 4.1.2. They include ultraviolet light, dehydration, high temperatures, freezing temperatures, and the presence of free oxygen. The survival or death curves indicate that microbial populations die off quickly (DA 1989).

Decontamination and decommissioning. Other than the effect of noise at the localized site area from D&D activities (building demolition), there would be no effect on ecological resources.

4.1.2 Human Health

Site Preparation and Construction. Human health effects during site preparation and construction for the proposed BSL-3 laboratory would be the same as for any small single-story construction project at LLNL. The effects would be very localized and would affect only site workers or visitors to the site. There would be no public human health effects. Routine construction activities have the potential for exposing workers or officially-sponsored site visitors to a number of common hazards including, for example:

- Biological hazards (e.g., snake bites, poison ivy, and insect stings);
- Electrical hazards (temporary electrical drops, excavations in areas with underground utilities, heavy-equipment lifting with nearby overhead utilities);
- Fire and explosion hazards (portable gasoline containers for generators and other gasoline-powered equipment, fuel transfers for onsite heavy equipment operation);
- Physical hazards (slips-trips-falls, walking-working surfaces, powered hand-tool operation, pinch-points, hoisting, motor-vehicle operation, excavations, ladders, noise, heat stress, cold stress, sunburn, dust, and particulates).

These hazards would be reduced or eliminated by compliance with Federal Occupational Safety and Health Administration (OSHA) regulations (29 CFR 1910.12, 29 CFR 1926, 29 CFR 1990), National Fire Protection Association (NFPA) codes (NFPA 1997, 1998, 2000), and the DOE directives which mandate these worker protection requirements for DOE facilities (DOE 1997, 1998).

UC workers at LLNL would not be directly involved in the construction of the BSL-3 facility, but they would be active in management, site inspections, and utility hookups. LLNL workers are currently involved in similar activities on site. Because of the expected limited involvement of LLNL workers in the construction of the new buildings, only minor effects to these workers are anticipated. The Proposed Action is expected to have no substantial effect on the health of any non-LLNL construction workers under normal operation conditions. Construction workers would be actively involved in potentially hazardous activities such as heavy equipment operations, soil excavations, and the handling and assembly of various building materials. Construction activities would take several months to complete. Appropriate personal protection measures would be a routine part of the construction activities (such as gloves, hard hats, steel-toed boots, eye shields, and ear plugs or covers).

Operations. The type and rate of injuries and illnesses expected during operation of the proposed BSL-3 laboratory would be the same as those demonstrated for CDC-registered laboratories, U.S. Army Biological Defense Research Program (BDRP) laboratories and existing biological research laboratories operated by LLNL. While the most obvious potential concern of operating a BSL-3 laboratory involves handling of infectious organisms (listed in the tables in

Appendix A), the proposed facility would have attributes of most laboratories in that it would have identified physical, electrical, and chemical hazards.

The proposed laboratory would not use radioactive materials, propellants, or high explosive materials, and the quantities of hazardous chemicals stored in the facility at any one time would be just a few liters each of chemical disinfectants (such as sodium hypochlorite or potassium hypochlorite) and biologic stabilizers (phenol). Chemicals such as paraformaldehyde would not be stored in the facility but brought in only when required for fumigation (the facility has a minimal amount of storage space). The hazardous chemicals used and stored would be tracked using ChemTrack (LLNL's computerized chemical inventory system) and handled according to the BBRP directives (LLNL 2000a), the Building 360 Complex directives for Biohazardous Operations (LLNL 2001a), and the LLNL Chemical Hygiene Plan for Laboratories (LLNL, 2001c). Use of biotoxins are discussed later in this section.

The potential for injuries and illnesses involving routine laboratory operations presents a greater health risk to workers than does the potential for injury and illnesses associated with handling infectious substances. Moreover, the combination of utilizing the guidelines, standards, practices and procedures established by the CDC, NIH, Human Health Services, and public health services together with BSL-3 safety equipment and facility safety barriers, results in an overall potential risk of illness to site workers or visitors from operations involving select agents that would be best characterized as minor. There would be no discernable public human health effect from routine BSL-3 laboratory operations at the proposed facility.

There has been an extremely low incidence of laboratory-acquired infections associated with operations in CDC-registered laboratories since the implementation of CDC-developed guidelines issued in 1974 (See Appendix A). Specifically, a recent bibliographic database (Collins 2000) based on reports starting from about the beginning of the 20th century and continuing up through August 2000 reveals substantial reductions in laboratory-acquired infections reported in the 1990s. There is a notable lack of reported cases in the literature relating to laboratory-acquired infections in the United States particularly in the last 10 years.

The experience of the U.S. Department of the Army (DA) at its BDRP facilities over several decades provides further insight to the potential for laboratory-acquired infection. The DA program underwent a programmatic NEPA evaluation in 1989, the *Final Programmatic Environmental Impact Statement, Biological Defense Research Program* (BDRP)(PEIS) (DA 1989). Up to time of that publishing, there were no occurrences of overt disease in laboratory workers handling infectious organisms within the DA BSL-3 facilities, although in 1980, one focal infection with *F. tularensis* occurred at the site of a puncture wound (DA 1989)." Since then there was one incident in 2000 (CDC 2000c) where a worker was exposed to *Burkholderia mallei* the causative agent of human glanders. The individual was hospitalized and shortly recovered. The BDRP PEIS (DA 1989) also estimated laboratory-acquired infection rates for their U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) facility for different biocontainment levels (roughly equivalent to the CDC BSL levels) over different periods of time. For their BSL-3 equivalent laboratory operations from 1960 to 1962 they estimated there were six laboratory-acquired infections for a rate of 2 per million man-hours worked. For their BSL-4 equivalent laboratory operations from 1960 to 1969, they estimated

seven laboratory-acquired infections for a rate of 1 per million man-hours worked. These infections included sub-clinical infections and mild illnesses where hospitalization was not required (DA 1989).

Overall, the BDRP PEIS estimated the rate of public infection from USAMRIID as less than 0.001 per 1,000,000 person-years and the risk of death to a laboratory worker for the "Defensive Period" (1970 to 1989) as 0.005 per 1,000,000 person-years (DA 1989). By way of comparison, the "Offensive or Weapons Period" (1954 to 1964) was associated with values for the risk of death to laboratory workers of about 5 orders of magnitude higher (DA 1989).

Experience with biological research laboratories at LLNL spans a period of many years. Based on information provided by the LLNL BBRP Assurance and Facility Manager, LLNL has operated BSL-1- and BSL-2-equivalent laboratories for at least the last 20 years without any infections associated with their operation (PC 2002). Also, there were no unintentional releases to the environment or to the public associated with the LLNL biological research laboratories. Additionally, the LLNL BBRP Assurance and Facility Manager reviewed available Occurrence Reporting and Processing System (ORPS) Reports (from the past 10 years). These reports include information on workers at BSL-1 and -2 laboratories at LLNL. The result of this review was that there have been no incidences of laboratory-acquired infections recorded for LLNL workers (PC 2002). Based on extensive experience with the safe handling of biological materials at LLNL and the Department of the Army, it is projected that the National Defense-related and scientific research to be conducted at the proposed BSL-3 facility would not result in significant impacts from normal operations to workers or the public.

Anecdotal reporting of human health issues elsewhere at BSL-3 or similar laboratories have indicated that while laboratory-acquired or laboratory-associated infections (specifically, the "all other" category of nonfatal injury and illness rates reported by the BLS) do occur, they should be considered abnormal events due to their infrequency of occurrence (Appendix B). As such, the human health effects of these events are discussed within this chapter in Section 4.2, Abnormal Events. There are a number of reasons that routine BSL-3 laboratory or similar laboratory operations do not normally produce infectious disease-related health effects to workers, their families, or the general public. In general, these are a result of the implementation of the comprehensive CDC and NIH guidelines (see Appendix A) that are based upon historical published accounts (anecdotal information) over many decades of experience in medical and bacteriological laboratories (CDC 1999) (see Appendix B).

Potential Pathways for Infectious Agents to Escape BSL-3 Containment. Potential means for infectious agents to leave the BSL-3 containment and possibly cause human health impacts would include five pathways. These are direct transmission,[19] vector-borne transmission,[20] vehicle-borne transmission,[21] airborne transmission[22], and water-borne transmission.[23]

[19] Direct transmission: Direct and essentially immediate transfer of infectious agents to a receptive portal of entry through which human or animal infection may take place. This may be by direct contact such as touching, biting, kissing or sexual intercourse, or by the direct projection (droplet spread) of droplet spray onto the conjunctiva or onto the mucous membranes of the eye, nose or mouth during sneezing, coughing, spitting, singing or talking (usually limited to about 1 meter or less) (Benenson 1995).

Direct Transmission. Operations as described minimize opportunities for direct transmission. Direct transmission would first require a worker to be exposed to an infectious agent. The likelihood of a worker inhaling or otherwise becoming exposed (for example, through cuts in the skin or ingestion) to an infectious agent would be extremely remote. While it would be very unlikely that a worker would be exposed, if exposed with a sufficient dose, it would be possible for them to be carriers[24] for those agents and through direct transmission expose others. This potential is further reduced through the intervention of effective vaccines or therapeutic measures (CDC 1999).

Vector-borne Transmission. The facility would be designed to severely limit the potential for possible vector-borne transmission through insects and rodents. The use of pest control programs (Appendix G of CDC 1999) would limit the potential for transmission of infectious agents from animals to humans.

Vehicle-borne Transmission. The primary concern for vehicle-borne transmission would be by the workers' clothing or skin and hair, as all other materials leaving the BSL-3 must go through a sterilization by autoclave or chemical disinfection. The guidelines established by the CDC and NIH, which would be followed within the proposed BSL-3 facility, are designed to reduce or eliminate this potential method of transmission. This would substantially reduce any potential for a worker to unknowingly transport infectious microbes from the facility.

Airborne Transmission. All air leaving the BSL-3 laboratories during normal conditions would exit through ductwork that is HEPA-filtered prior to emission through stacks on the building roof. HEPA filters are rated as 99.97 percent efficient at a most-penetrating "design point" of 0.3 microns[25] diameter as tested by dioctyl phthalate (DOP) particles (NSC 1996). This means that HEPA filters are designed to remove at least 99.97 percent of all the particulates that hit the filters, even in the most-penetrating sizes of 0.1 to 0.4 microns. The remaining particles (less than 0.03 percent) can penetrate or pass through the filters. The number of viable vegetative microorganisms after HEPA filtration would be negligible. Filters are made from randomly laid non-woven natural or synthetic fiber materials made into a flat sheet that is pleated and placed

[20] Vector-borne transmission can include mechanical or biological transmission of infectious agents. Mechanical transmission includes carriage by crawling or flying insects through soiling of feet or proboscis or by passage of organisms through its gastrointestinal tract. This does not require multiplication or development of the organism. Biological transmission includes the propagation (multiplication), cyclic development, or a combination of these (Benenson 1995).

[21] Vehicle-borne transmission is the transmission of infectious agents through contaminated inanimate materials or objects such as handkerchiefs, soiled clothes, surgical instruments, water, food, and biological products (Beneneson 1995).

[22] Airborne transmission is the passage of microbial aerosols to a suitable portal of entry, usually the respiratory tract. Microbial aerosols are suspensions of particles in the air consisting partially or wholly of microorganisms (Benenson 1995).

[23] Water-borne transmission is the transmission of infectious agents through contamination of water. It can be considered a subcategory of vehicle-borne transmission.

[24] A carrier is a person or animal that harbors a specific infectious agent without discernable clinical disease and serves as a potential source of infection (Benenson 1995).

[25] A micron, also known as a micrometer, is one millionth of a meter or four hundred thousandths of an inch.

into a filter container. Pleating increases the surface area and improves filter loading and reduces air resistance. HEPA filters have fiber diameters ranging from 0.65 to 6.5 microns in three diameter groupings. The process of aerosol filtration does not simply rely on the size of the opening between fibers, but uses a number of physical properties of air movement around fibers to capture the particles. These forms of capture are called interception, sedimentation, impaction, and diffusion. Electrostatic attraction also plays a part in capturing small particles and the fiber material is often selected specifically to enhance this effect (for example, electret fibers and wool resins). The exact combination of capture mechanisms varies. Larger particles are generally removed by impaction and interception while light particles are removed by diffusion and interception. These mechanisms remove essentially all particles larger than 0.6 microns in diameter and low flow rates let diffusion remove most all particles below 0.1 micron (NSC 1996). A "most-penetrating particle size" exists between 0.1 and 0.4 microns which is the reason for testing and certifying HEPA filters for particle removal at 0.3 microns (NSC 1996). The DOP test is highly conservative relative to microorganisms that may have sticky cell-walls and/or protuberances such as, flagella and pili (protein fibers 0.5 to 20 microns in length) which help them adhere to other cells. Bacterial spores are larger than their vegetative cells and have charged surfaces that promote attraction to other surfaces. Being sticky or with charges on their surfaces promotes their capture by the HEPA filter.

NNSA acknowledged in the LLNL Supplement Analysis for Continued Operation of Lawrence Livermore National Laboratory and Sandia National Laboratories, Livermore (March 1999, DOE/EIS-0157-SA-01) the issue of reduced removal efficiency of HEPA filters for particles in the size range from 0.1 micron to 0.3 microns. The study which provided this information was from a dissertation written by Ronald C. Scripsick (Los Alamos National Laboratory Report, LA-12797-T, 1994). Even though the most-penetrating particle size in his study was slightly smaller than the HEPA filter "most-penetrating design point" of 0.3 microns, his results still showed a 99.97% removal efficiency or higher in the range from 0.148 to 0.196 microns.

HEPA filters at the LLNL BSL-3 facility (including those in the BSCs) would be tested annually and replaced as necessary. Given the proposed operations of the facility, there is no expectation that the HEPA filters would become moisture-saturated or torn – the two major reasons for HEPA filter failures.

Regardless of the presence or failure of HEPA filters, many environmental factors effectively and naturally kill airborne microbes in their vegetative state. These factors include ultraviolet light, dehydration, high temperatures, freezing temperatures, and the presence of free oxygen. Together these factors account for a substantial reduction in the number of microorganisms. While outdoors, the sun, temperature, and other atmospheric conditions ensure that microbial populations die off quickly, generally within minutes. Mathematical predictions of the potential survival of certain types of microorganisms in the environment estimate that only about 0.01 percent are able to resist the chemical or physical inactivation found in the outside environment (Mitscherlich and Marth 1984).

Water-borne Transmission. Potable water would not be affected by the implementation of the Proposed Action. Facility design features, such as backflow preventers and State of California-adopted uniform plumbing code requirements would prevent microbes within the facility from migrating back through the water supply piping to the public. Water exiting through the sink

drains would be diverted to a retention tank where it would be disinfected before being sent to the sewer system and the LWRP facility.

According to the EPA Surface Water Treatment Rule (40 CFR 9, 141, and 142), public water treatment systems must physically remove or inactivate 99.9 percent of the cyst-forming protozoans *Giardia spp*. and *Cryptosporidium spp*. Treatment system operators comply with this rule by determining the amount of chlorine and contact time (along with temperature and pH) that it takes to produce the required killing of pathogenic microorganisms. Contact time on the order of hours along with a measurable free available chlorine content meets this requirement.

Animal Handling Operations. Appendix B presents some background information on laboratory-acquired infection due to animal handling. The most common effect is for the animal handlers to develop allergies to the hair, dander, urine, and possibly serum of rats or mice. This is, however, very controllable with adherence to standard operating procedures, maintenance of a high standard of quality for anything entering the cages, utilization of cages designed for high standards of ventilation and cleanliness, and a good overall design for the rodent facility. The proposed facility would use a state-of-the-art ventilated caging system similar to the one shown in Section 2. These systems have high rates of exchange air, are designed for easy cleaning, and are HEPA-exhausted for worker protection and for research quality maintenance. Also, once exposed to a pathogen or toxin, the rodents would not leave the cages except inside a BSC. Following proper recognized procedures would help to insure that workers aren't exposed to pathogens from the rodents.

When handling human pathogens or zoonotic disease-causing agents (capable of being exchanged between humans and other animals) workers would use personal protective equipment (PPE) and would be either immunized and/or would have medical treatment available (prophylaxis) for the specific pathogen. Human pathogens for which there is no immunization or prophylaxis would not be handled in the proposed BSL-3 laboratory in accordance with the BMBL guidelines.

Historically the greatest opportunity for contracting a disease from the animals is through an inadvertent needlestick (autoinjection) or from bites and scratches. These can be averted by adhering to standard operating procedures (SOPs) and safety procedures using safety equipment that virtually eliminates these occurrences. These SOPs would be in place, along with the use of appropriate equipment in the proposed BSL-3 facility, prior to operation.

Rodent Challenge Studies.

Activities planned for the proposed action include aerosol-studies using rodents (mice, rats, and possibly guinea pigs). These studies would only be done inside a BSC that meets all currently applicable BMBL requirements (according to WorkSmart Standards) for the materials involved. One possible aerosol-challenge device, a collision nebulizer, would have its reservoir filled while in the BSC from other containers. The rodent would be challenged with the aerosol and the rodent would be placed into a clean cage. The nebulizer would be cleaned and chemically disinfected while still in the BSC. Procedures would be written and adhered to that would insure the device could not be removed from the BSC and be capable of generating an aerosol. Compressed air is necessary for generating the aerosol and it would be immediately disconnected

at the end of the process of challenging the rodent. After removal from the BSC, the device and all its parts would be put into an autoclave to insure sterilization.

Biotoxin Research.

The handling and use of a biologically-derived toxin is essentially the same as the handling of a hazardous chemical. As explained in Appendix B, there are three routes of exposure, but the most likely route of exposure would be the inadvertent needlestick. The probability of being exposed to a biotoxin if appropriate safeguarding and other safety procedures are followed would be extremely low. The Proposed Action facility would have appropriate procedures in place prior to operation of the facility.

Decontamination and Decommissioning. When the time comes for D&D of this facility, there would be no pathogens or toxins in the facility after it has been treated with chemical disinfectants and fumigated. Therefore there would be no human health effects related to biological materials expected from D&D activities. Also, no human health effects would be expected due to the deconstruction activities themselves since OSHA and EPA-type health, safety, and environmental protection procedures to control dust and noise would mitigate these potential issues.

4.1.3 Air Quality

Site Preparation and Construction. During site preparation and construction, the use of heavy equipment would generate combustive-engine exhausts that would contribute to air pollution. However, since there would be very few of these pieces of equipment and their use would be limited in time, the potential effect on ambient air quality would be temporary and localized. During construction there would be a temporary increase in particulate emissions. Operation of construction vehicles such as dump trucks, cranes, and those involved in waste disposal actions would also produce temporary and localized emissions of other air pollutants. Mobile sources, such as construction and waste transport vehicles, would produce other air pollutants (such as sulfur oxide), but the quantities would be minimal relative to the amount of mobile sources already in the area Air District.

Operation. Air quality effects during the operation of the facility relate in part to the generation of gas-combustion engine emissions from private motor vehicles during workers' commutes to and from work. Almost all of the workers are already working in adjacent buildings, so there would be no net effect to air quality from the travel of these individuals. Even the addition of a few new workers (if needed) would not produce a substantial contribution to air emissions. Since vehicle use would not change substantially as a result of operating the new facility, emissions from automobiles would not noticeably increase within the Building 360 Complex Area.

The emergency generator designated for the proposed BSL-3 facility is already operational at an adjacent building and therefore would not add to air emissions. No additional emergency generators, boilers, or other fuel-burning equipment would be added as a consequence of building and operating the proposed BSL-3 facility.

Periodic use of disinfecting gases could be part of the routine operation of the facility. These gases or vapors, such as formaldehyde (from paraformaldehyde) would not affect the local air quality since they would be inactivated at the end of each use. Effects of these gases, if any, would be temporary and localized and would dissipate very quickly. HEPA filtration of all laboratory exhausts removes virtually all biological particles and therefore there would be no incremental increase due to BSL-3 laboratory operation.

Decontamination and Decommissioning. Air emissions from D&D activities would consist of particulate dust emission due to demolition activities (controlled by water application) and mobile emissions due to trucks hauling building debris to the local landfill. These trips to the landfill would be minimal due to the small size of the building.

4.1.4 Noise

Site Preparation and Construction. It is possible that noise levels would exceed at least for periods of several minutes at a time the 8-hour 85-dBA threshold limit value (TLV) (ACGIH 2000), but only during daylight hours and only in the immediate vicinity of the site preparation and construction activity. Members of the public would not be exposed during the daytime or nighttime to noise levels exceeding city planning and zoning code standards (ambient noise level greater than 75 dBA beyond the boundaries of the site, nor greater than 60 dBA at the boundary of a residential district) (City of Livermore 2000). This is predicated on the distance of the proposed facility being about one-half mile to the nearest residence (near West Gate, Figure 1-3).

Heavy equipment such as front-end loaders and backhoes would produce intermittent noise levels at around 73 to 94 dBA at 50 ft (15 m) from the work site under normal working conditions (Cantor 1996; Magreb 1975). Construction truck traffic would occur frequently but would generally produce noise levels below that of the heavy equipment. The finishing work within the building structures would create noise levels slightly above normal background levels for office work areas. Noise levels may go up to around 80 dBA at the work site if light machinery is used in this stage of construction (Cantor 1996). Workers would be required to have hearing protection if site-specific work produced noise levels above the LLNL action level of 80 dBA for steady-state noise. Sound levels would be expected to dissipate to background levels well short of the LLNL boundaries.

The additional construction-worker personal vehicular traffic would not be expected to increase the present noise level produced by vehicular traffic on Vasco and Greenville Roads and East Avenue during rush hour. The vehicles of construction workers would remain parked during the day and would not contribute to the background noise levels during this time.

Operation. The expected noise levels during operation of the proposed BSL-3 facility would be consistent with those of other existing LLNL bench-top research laboratory facilities. These noise levels would be due to vehicular traffic passing through the facility area and from the facility's HVAC system operation. Residential areas would not be exposed to ambient noise level greater than 75 dBA beyond the boundaries of the site, nor greater than 60 dBA at the boundary of a residential district (City of Livermore 2000).

Decontamination and Decommissioning. While there might be more trips from heavy equipment (dump trucks) during this phase of activity, the noise levels and extent of noise to the LLNL boundaries would be no more than that for site preparation and construction, or from other routine site infrastructure maintenance and construction activities.

4.1.5 Waste Management

Site Preparation and Construction. The incremental increase in waste materials produced during this phase of work would be minimal with respect to the waste production of the entire LLNL facility (2,363 tons in 2000, LLNL 2001b). Construction debris primarily comprised of wood, metal, asphalt, paper and plastic would be the typical waste expected to be generated during construction of the BSL-3 facility building and tearing up of associated parking area. This solid waste would probably be disposed at the Altamont Landfill (Alameda County Landfill). Additionally, the project could generate very minor amounts of excess uncontaminated soil from excavation activities. The soil could be stockpiled at an approved soil material management area for future use or disposal.

Operation. No additional waste disposal facilities would be developed as a result of the Proposed Action. Waste quantities and disposal practices were discussed in Chapters 2 and 3. The incremental sanitary sewer waste production associated with the operation of the facility would be minimal (on the order of 10,000 gal per yr or 37,900 liters per yr) with respect to the total waste volumes generated by the entire LLNL facility (256,000 gal per day or 970,000 liters per day in 2000) (LLNL 2001b) and negligible with respect to the City of Livermore's sewer system discharge (6.5 million gal per day or 25 million liters per day in 2000) (LLNL 2001b). Retention tanks would be used to capture research-related biological liquid waste to ensure disinfection is adequate prior to discharge to the sanitary sewer system. There would be no need for waste accumulation areas since minimal quantities of hazardous waste would be generated (hazardous chemicals would typically be used up in process or leave the building as a stabilizing product for microorganisms and biological material).

Decontamination and Decommissioning. At the conclusion of operations, the building would be fumigated and surfaces would likely be washed down with dilute concentrations of household bleach to kill any pathogens. No appreciable hazardous waste would be generated from this operation. D&D of this facility would mainly generate solid waste which would be comprised almost entirely of construction debris. Construction debris is comprised primarily of wood, concrete, gypsum wall board, metal, asphalt, paper and plastic and would be typical of waste expected to be generated during demolition of any laboratory or light-industrial facility. This solid waste would probably be disposed at the Altamont Landfill (Alameda County Landfill).

4.1.6 Geology/Soils/Seismology

Site Preparation and Construction. Except for the temporary disturbance of up to a depth of a few feet on parts of one-quarter acre of land during site preparation and construction, there would be a negligible effect upon geology, soils, or seismicity. Soil erosion prevention measures (application of the SWPP Plan for mainsite LLNL activities) would be in place during the construction phase to minimize erosion from stormwater. Also, dust suppression measures

would be employed to minimize wind erosion. The disturbed construction areas not covered by the building footprint or by parking areas would be reseeded.

Operation. There would be no effect from the proposed BSL-3 facility operation on geology, soils, or seismicity. Soils surfaces not covered by the building footprint or not paved would be landscaped to control erosion from stormwater runoff.

Decontamination and Decommissioning. Except for the temporary disturbance of portions of up to one-quarter acre of land during building demolition, there would be a negligible effect upon geology, soils, or seismicity. As noted above, soil erosion prevention measures would be in place during this phase to minimize erosion from stormwater. Also, dust suppression measures would be employed to minimize wind erosion. Once demolished, the building debris would be removed and the site would be stabilized for water and wind erosion.

4.2 ANALYSIS OF ABNORMAL EVENTS AND ACCIDENT SCENARIOS

4.2.1 Site Preparation and Construction

The site preparation and construction part of Section 4.1.2 deals with routine injury and illness related to nonresidential building construction. Routine accidents are those that commonly occur on construction sites (for example, slips, trips and falls). Because they are routine, they are not considered abnormal events, nor do they take into consideration accidents with more substantial consequences, such as those resulting from catastrophic events.

4.2.2 Operation

This section evaluates potential abnormal event scenarios for operation of the BSL-3 facility that have a reasonable probability of occurrence and scenarios that involve malicious acts. Abnormal events are all selected on the basis of historical knowledge at similar facilities over many years of operation involving similar laboratory activities. The first discussion covers the potential for laboratory-acquired infections which, in the literature, is considered both a routine health risk and as an accident due to the frequency of exposures through, for example, needlesticks. The accident potential is discussed in Sections 4.2.2.1 through 4.2.2.3. The following sections discuss the potential for laboratory-acquired infection, a laboratory accident, and the potential for transportation accidents. Section 4.3 describes the potential for terrorist acts.

4.2.2.1 Analysis of Seismic Events for Facility Operation

The facility has the potential to be affected by earth movements due to earthquakes. Seismic analyses of the Livermore Site were performed to quantify the hazards (DOE 2005). The analyses identify the probability of exceeding a given peak ground acceleration. The 2005 SWEIS lists the maximum horizontal peak ground accelerations at the Livermore Site for varying return periods of 500 and 1,000 as 0.38 *g*, and 0.65 *g*, respectively (the technical basis for these peak ground acceleration values is provided in Appendix H of the SWEIS) (DOE 2005). The document also considers the effects of an earthquake with a peak ground acceleration of 0.73g.

The facility is capable of withstanding the g-force predicted for a return period of 1000 years without loss of containment or structural integrity (i.e., Performance Category-2, LLNL 2001c). As a result of conservative assumptions in the design process, damage to the structural systems from a horizontal peak ground acceleration of 0.73 g is expected to be very slight. Nonstructural elements, including ceilings and cladding, could experience minor cracking but would remain secured.

4.2.2.2 Analysis of Abnormal Events and Accidents for Facility Operation

Laboratory-acquired infection. Laboratory-acquired infections are those infections acquired by workers due to the routine performance of their duties. When the exposure to an infectious agent occurs during an event, it is often considered an accident (such as a needle-stick). When the exposure occurs incidentally during contact with a contaminated surface, it is considered a routine health risk. The following discussion deals only with the accidental laboratory-acquired infection.

Many sources were reviewed that compiled laboratory-acquired infection statistics (CDC 1999; Collins 2000; Collins and Kennedy 1999; Pike 1979, 1976; Pike et al. 1965; Sewell 1995; and Sulkin and Pike 1951, 1949). Much of these data are reviewed and discussed in Appendix B, Section B.1. The most recent bibliographic compilation of microbial disease reports (Collins 2000) covers the period from the turn of the century up until August of 2000, and shows a noticeable lack of laboratory-acquired infection reports in the United States during the last ten years. The Department of the Army (DA) *Final Programmatic Environmental Impact Statement, Biological Defense Research Program* (BDRP) (PEIS) (DA 1989) states that since 1976, there have been no occurrences of overt disease in laboratory workers handling infectious organisms within BSL-3- and BSL-4-equivalent BDRP laboratory facilities. The DA estimated the risk to its workers for laboratory-acquired infection for the period from 1970 to 1989 as 0.005 per 1,000,000 person-years (DA 1989). This was a period of heavy activity using large volumes of infectious agents. The incidence of infection appears to be much lower today in large part due to decreased laboratory activity levels since 1968, and in part due to greatly improved preventive measures.

Control of infection in laboratories has achieved a high level of sophistication, to the point that virtually no reports of infection occur in microbiological laboratories. The CDC says that common acceptance of standard laboratory practices indicates that laboratory-acquired infections should be virtually non-existent today (CDC 1999). However, they do still rarely occur and the primary route of exposure is through autoinnoculation by the unintentional injection or needle-stick (Sewell 1995). Needles would be used in the proposed BSL-3 facility. Broken glass with sharp edges could result from accidents with (infrequently used) glassware. Broken glass, needlesticks or even scalpels present a low likelihood of exposure but are obvious when they happen and can be promptly treated with antibiotics, antiviral drugs, or other appropriate medical strategies. The potential for accidental laboratory-acquired infection by these means would be reduced to the improbable level of occurrence.

Since this Environmental Assessment was originally issued in 2002, the CDC has investigated several laboratory incidents involving exposure of personnel to biological agents that resulted in

infection. For example, in November 2004, three cases of tularemia were reported for Boston University laboratory researchers working with the live vaccine strain of *Francisella tularensis* (BPHC 2005). In February 2006, a worker at Texas A&M University was exposed to the select agent *Brucella* during cleaning of an aerosol chamber following an experiment (GAO 2007). Three Texas A&M researchers also tested positive for the bacterium that causes Q fever in April 2006 (Houston Chronicle, 2007). These and other exposures to biological agents during laboratory incidents since 2002 resulted only in treatable illness, and are not known to have resulted in either death or secondary infections. The relatively small number of accidental exposures during this 5-year period supports NNSA's assertion that although it is possible, it is improbable laboratory staff would acquire an accidental laboratory-acquired infection during the operation of the proposed BSL-3.

The Laboratory Release Accident Scenario. The potentially hazardous material to be handled in the proposed facility would consist of infectious microorganisms in containers holding liquid suspensions or on semi-solid media. Accident scenarios usually envisioned for DOE facilities would normally be seen to exacerbate or enhance a release or spread of the hazardous materials, but for the BSL-3 facility would potentially render these materials innocuous (heat, fire, sunlight, and wind). These would be avoided when working with microorganisms and would usually result in microorganisms being killed. Consequently, catastrophic events such as earthquake, fire, explosions and airplane crashes, normally considered as initiating events in DOE radiological or chemical accident analyses, were viewed as having the potential to actually reduce the consequences of microbiological material releases. An earthquake, explosion, or similar event that would result in a breech or rupture of the facility's walls would be bounded by the hypothetical centrifuge-accident analysis of a *Coxiella burnetti* release from the proposed BSL-3 facility structure described later in this section. The probability of catastrophic events (due to earthquake) is already very low. The low probability of an earthquake capable of rupturing the facility containment, coupled with an additionally low probability of such an event occurring during a daytime activity where microorganism containment would be vulnerable, also makes it an unlikely event. The proposed laboratory hypothetical centrifuge accident-release scenario, which itself is very unlikely due to the simultaneous occurrence of several events/conditions that must be combined to produce a release, bounds the catastrophic release scenario. This accident-release scenario is the bounding biological accident-release scenario in the 2005 Sitewide EIS (DOE 2005) for all biological research activities at the Livermore Site. Appendix B provides background information on microbiological accidents. This scenario is also very similar to the BSL-3 accident analyzed in the recently published Final Environmental Impact Statement for the Construction and Operation of the New USAMRID Facilities at Fort Detrick, MD (USAMRMC 2006).

The BSL-3 facility would have only a few operations or activities that would hypothetically place up to 1 liter quantities of material containing infectious organisms at risk at any point in time. These operations or activities would occur at infrequent times and a release to the environment from a catastrophic event would require several simultaneous conditions to coexist: a worker is transferring a quantity of infectious material when the catastrophic event occurs; the containers aren't properly sealed; the entire set of containers is dropped; the containers break open; and the catastrophic event simultaneously causes a structural breach in the BSL-3 containment walls. Engineering and procedural controls minimize opportunities for this

hypothetical scenario. For example, culture samples would be kept in locked freezers or within incubation chambers most of the time and would not become aerosolized in such an event. Therefore, catastrophic events capable of resulting in a substantial release of microorganisms from the confinement of the facility (specifically at greater than infectious dose quantities) would be unlikely to occur.

A literature search and discussions with BSL-3 laboratory regulators and operators (CDC, NIH, and the U.S. Army) revealed no incidents of infectious materials released from catastrophic accidents at microbiological laboratories. According to the U.S. Army (DA 1989), the likelihood of such catastrophic occurrences is too small to be considered as reasonably foreseeable. No such event has occurred in the more than 50 years in which the military has been conducting biological defense research activities (DA 1989). Based on this historical information, this hypothetical scenario was not analyzed further in this EA.

Historical information suggests that other types of accidents would be reasonably foreseeable; these could involve infectious material. Accidents involving the production of aerosols during the use of normal laboratory equipment such as centrifuges, blenders, homogenizers, shakers, sonicators, and mixers are reported. According to *Laboratory-Associated Infections and Biosafety*, this is the second most common route of exposure, the first being laboratory-acquired infection due to needle-sticks (Sewell 1995). Even though these accidents are more frequently reported, they rarely result in workers actually contracting diseases due to the use of vaccines and drug therapies.

Appendix B describes accident scenarios used in other NEPA documents for analysis of BSL facilities. One accident scenario that was analyzed involved the release of a biotoxin from the common soil bacterium *Clostridium botulinum* (BMI 1993). The accident scenario analysis resulted in an estimated potential release of biotoxin that was several orders of magnitude lower than the dose at which "no effect" resulted. Another NEPA document (DA 1996) accident scenario postulated the release of *Brucella spp*. bacteria transmitted by direct contact with animal secretions. The qualitative analysis indicated no release to the public.

Another relevant NEPA accident analysis was prepared by the U.S. Army for its BDRP PEIS covering several facilities across the United States and is considered most relevant to the Proposed Action. The DA has for decades operated a series of the most extensive infectious agent laboratory facilities in the world. This PEIS addresses the entire BDRP, including multiple facilities, and involves a far greater level of operations than NNSA proposes at LLNL. The reason this accident analysis should be considered relevant to the proposed BSL-3 facility at LLNL is because the PEIS analyzed BSL-3 facilities with engineering and operating characteristics similar to those proposed for LLNL, such as similar HVAC system designs for negative pressure and air turnover; the facilities having similar HEPA filtration; the facilities would operate under the same procedures established by CDC (CDC 1999; 32 CFR 627); and the facilities would be designed to handle the same types of microorganisms.

Important differences between the DA's accident analysis modeling and the conditions at the proposed LLNL BSL-3 facility would be due to the model's input parameters (also called modeling assumptions) associated with the meteorological conditions and the proximity to non-involved workers and the public. The DA's accident scenario assumes to have essentially non-

windy site conditions and nearby non-involved facility workers and members of the public. The LLNL site is usually windy and members of the public would usually be a minimum of one-half mile away. The differences in the DA's modeling assumptions and the conditions at LLNL result in the accident analysis being much more conservative for LLNL conditions than the analysis modeled at the DA site. Therefore, the effects of such a scenario, if it were to actually occur, would be much less adverse at LLNL than those hypothesized for a DA site.

The BDRP PEIS accident scenario is referred to as the Maximum Credible Event (MCE) in accordance with the DA's *Biological Defense Safety Program, Technical Safety Requirements* (32 CFR 627). The microorganism chosen for the MCE accident is *Coxiella burnetii (C. burnetii)*, the organism responsible for causing Q fever. According to the *Control of Communicable Diseases Manual* (Benenson 1995), this organism has an unusual stability, can reach high concentrations in animal environments, and is relatively resistant to many disinfectants. The CDC states that *Coxiella burnetii* probably presents the greatest risk of laboratory infection. The organism is highly infectious and remarkably resistant to drying and other environmental conditions. The estimated human infective dose (HID) with a 25 to 50 percent chance of contracting the disease through the inhalation route for Q fever is 10 organisms (CDC 1999).

The rickettsial microorganism*, C. burnetii,* is considered representative of all types of BSL-1, BSL-2, and BSL-3 laboratory microorganisms (bacteria, rickettsia, viruses, fungi, parasites, and prions) because it is highly durable, infectious, and transmissible, and has excellent environmental survivability. Other types of microorganisms were considered for accident scenarios but rejected for specific analysis because they represent a relatively lower human health hazard (fungi and parasites) or have a generally lower environmental survivability (specifically, the prions and viruses). All animal prions and human parasites are Risk Group 1 or Risk Group 2 microorganisms. Only one fungus identified by the CDC requires BSL-3 and all the rest only require BSL-2 or below (CDC 1999). Many viruses require BSL-3 procedures and equipment but cannot survive long in the environment without a host such as a human or other animal. Bacteria and their subcategory, rickettsia, represent a high risk to human health and many require BSL-3 or BSL-4 procedures and equipment.

Of the bacteria, *C. burnetii* is a durable rickettsia that can be handled in the laboratory with little or no loss in viability. It can survive being aerosolized and remain viable, although once separated from a nutrient food source, it dies off at a slow rate. This microorganism can be as infectious as any other microorganism. The CDC reports that exposure to only 10 microorganisms can cause an individual with normal immunocompetency to develop symptoms of disease. Others report this to be as low as five microorganisms or possibly even one (CDC 2001b). *C. burnetii* has the added "advantage" of being one of the CDC "select agents" (42 CFR 72) and is also considered a critical biological agent[26] (CDC 2000a) (also called Bioterrorism agents).

[26] The CDC Strategic Planning Workgroup has prepared a plan to address the deliberate dissemination of biological and chemical agents. Certain organisms are designated as "critical biological agents" and are assigned priority ratings based on characteristics that pose a risk to national security.

The scenario for the MCE (detailed in Appendix B) involves an instantaneous release of a fixed amount of infectious material as follows. A worker uses a BSC to place a 1-L slurry of *C. burnetii* into six 250-ml polypropylene centrifuge tubes. The worker fails to insert the O-rings or tighten the centrifuge caps, which are the screw-on type. The worker takes the tubes out of the BSC and inserts them into a free-standing centrifuge and turns the equipment on. All six tubes leak, with some of the slurry leaking into the rotor, and some leaks into the centrifuge compartment. Most of the slurry that is not aerosolized settles (99 percent) and 90 percent of that which settles becomes droplets inside the chamber. The worker opens the centrifuge and notices the leak. The worker obtains help from two co-workers, and four more workers enter the laboratory not knowing what has happened. The room air exhausts to the outside of the building through a stack on the roof after passing through two sets of HEPA filters that, for conservatism, were estimated to have a filter efficiency of only 95 percent.

For the workers, the accident produces 9,900,000,000 (9.9×10^9) airborne HIDs at a 50 percent rate of contracting the disease (HID_{50} or ID_{50}) which occurs in a 3 ft^3 of space above and around the centrifuge. This volume of contaminated air then disperses throughout the room in response to the ventilation system flow characteristics (for example, the volume of air in the room and the HVAC ducting, and the room air turnover rates). The excited worker who opened the centrifuge is potentially exposed to 100,000 HID_{50} due to a higher rate of respiration at l5 L or 0.5 ft^3 per minute (normal is 4 to 6 L or 0.14 to 0.21 ft^3) (NSC 1996). The two co-workers coming to his assistance receive an only slightly lower dose. The other four workers incidentally exposed receive 100 to 300 HID_{50}.

The result to the general public was calculated for this scenario using a gaussian plume dispersion model under relatively calm wind conditions (stronger winds would dilute more readily). At the maximum air-concentration described above, the model predicted less than 1 HID_{50} per liter of air at a distance of 7 ft (2 m) from the stack, less than 0.1 HID_{50} per liter of air at 53 ft (16 m) from the stack, and less than 0.01 HID_{50} per liter of air at a distance of 125 ft (38 m) from the stack. The concentrations dissipate readily after reaching these maximums since the accident scenario resulted in a one-time instantaneous release.

This hypothetical accident can be used as a bounding accident analysis for the Proposed Action LLNL BSL-3 facility. However, it is exceedingly conservative. From a slightly more realistic perspective, there are some aspects of this accident scenario that would significantly lessen the possible outcome to the point that it would not produce even one HID_{50} at the end of the stack in the case of the proposed facility at LLNL. Some of these are:

- Cultures in a centrifuge in their stationary phase (with 10^8 cells per ml) would quickly pack to the bottom of the centrifuge tube and the upper liquid phase that would become aerosolized would have very few cells (depending upon when the accident occurred in the cycle) – therefore the concentration of cells in the aerosol would likely be many orders of magnitude below that used for the analysis (extremely conservative).
- At LLNL (and most small BSL-3 laboratories) normally only two workers would be allowed in a BSL-3 laboratory at a time for safety reasons.
- In an emergency response mode, the responder would enter only after ascertaining the risk and donning appropriate personal protective equipment.

- The worker(s) would have the appropriate prophylaxis available or immunization prior to working in the laboratory and would not become symptomatic.
- If all the room air were doubly HEPA-filtered with each at a minimum of 95 percent efficiency, the overall filtration would be 99.75 percent efficiency (passing through the first filter with 95 percent efficiency would leave 5 percent to pass through and the second filter would remove 95 percent of the 5 percent – resulting in 99.75 percent overall removal efficiency).
- HEPA filtration is rated at 99.97 percent efficient at the most penetrating design point of 0.3 microns using the DOP standard for calibration and measurement which is a uniform size, shape, and non-charged. Removal efficiency is not based upon size alone because there are several physical processes which actually cause the particulate removal. Penetration of larger- or smaller-sized particulates than 0.1 to 0.3 microns (the most penetrating size range) is negligible (less than 0.03 percent). Actual microbes, especially wet, have biofilms on their surfaces, are not uniform in size or shape, agglomerate together, and would not likely penetrate even at 95 percent efficiency because of their physical characteristics.
- The hypothetical accident results of even these extremely small effects rely on compounding of several independent actions whose combined probability of sequential occurrence would be extremely low (o-rings are not inserted, caps not screwed on properly, all six tubes leak, the worker opens the lid not realizing the tubes leaked, the worker gets two other workers to come over and look, and four more enter not knowing what has happened).
- The aerosol efficiency of 0.1% assumed for the scenario is at least one order of magnitude higher than would be likely in a real situation.
- The modeling assumptions (as described in Appendix B) are for the most stable open-terrain conditions and LLNL is both urban and non-open due to the predominance of buildings and trees which increase turbulence and tortuosity (i.e., mixing) and settling.
- Increases in wind speed over the modeled rate of 4.5 mph would increase aerosol dilution while humidity (not considered by the model) enhances the settling of particulates and would also decrease airborne concentrations.
- The normal high rate of air-changes for a laboratory like this would not generate a single "concentrated slug" of aerosolized material to exit the building as proposed in the model.
- Last, but not least, Risk Group 3 agents (those handled in BSL-3 laboratories) are associated with serious or lethal human diseases for which preventative or therapeutic intervention may be available (high individual risk but low community risk).

The conclusion is that members of the public would have a very low likelihood of being exposed to even a small fraction of one HID_{50}. At LLNL, the nearest member of the public is about one-half mile away. Adverse health effects to uninvolved workers in adjacent buildings or the public would be extremely unlikely to develop from this scenario. Similarly, adverse effects to the environment from the accidental release of non-indigenous organisms would be extremely unlikely as well.

4.2.2.3 Transportation Accident

Infectious substances (etiologic agents) in transit on the Nation's highways, railways, and airports are regulated by the U.S. Department of Transportation (DOT) regulations (49 CFR 171, 172, 173, and 178). As a consequence of these regulations, the DOT tracks and reports accidents and, in particular, hazardous materials incident reports. The general population risk report by DOT from 1994 to 1998 from all hazardous materials transportation is 1 in 8,129,000, or as otherwise stated, 0.11 fatalities per million shipments (DOT 2001a). By comparison, the general population risk per year for motor vehicle accidents is 1 in 6,300 or 1.7 deaths per 100 million vehicle miles (161 million kilometers). The number of hazardous materials shipments is about 800,000 per day with at least 10,000 involving waste hazardous materials identified generally as medical wastes and various other hazardous materials. For the hazardous materials category that includes infectious substances, about 80 percent of these shipments are carried by truck with the remainder carried by rail (DOT 1998). There are an estimated 4,300 non-hospital waste generating facilities (laboratories) that are potential generators of medical waste and other kinds of infectious substances including diagnostics specimens. These facilities generate 73,037 tons per year of infectious medical waste and ship about 200 tons (181,000 kg) per day (DOT 1998). Information extracted from the DOT Hazardous Materials Information System (HMIS) database (DOT 2001b) on infectious substances transportation from 1995 to 1999 show that infectious substance incidents are too few to even be ranked. There is, however, an apparent national increase in overall hazardous materials incidents, which rose from 14,700 in 1995 to 17,069 in 1999.

LLNL has never had a biological-material transportation accident (PC 2002). However, an incident occurred in August-September 2005 in connection with a shipment of a collection of vials containing the select agent Bacillus anthracis (anthrax) to two laboratories, one located in Florida and the other in Virginia. At one lab, workers unpacking the shipment discovered that some of the vials had leaked from their primary containers into the inner packaging of the secondary container. However, the material did not escape from the secondary container into the packing material within the tertiary shipping container. Although the unpacking process was conducted in a laboratory, it was not conducted in a Biological Safety Cabinet (BSC), as required, which resulted in five workers being exposed to liquid from the packages while unpacking the secondary containers. These employees received medical treatment as a precaution and there were no adverse health effects. No liquid penetrated the outer shipping container and there was no public release. At the second lab, discrepancies were noted between the shipping inventory and the samples in the container. As required by 42 CFR 73, the recipients of the shipments notified the Centers for Disease Control and Prevention (CDC) of these problems. As a result, the CDC suspended all LLNL transfers of select agents. An NNSA Occurrence report was filed regarding the incident and LLNL issued a full stand-down of all select agent work.

An analysis of the shipping incident resulted in multiple corrective actions to strengthen LLNL's packaging and transportation program for select agents and other bio-hazardous materials at LLNL. Actions taken to prevent recurrence included an expansion of the Select Agent Security Plan, additional training related to packaging and shipping regulations, clarifying roles and responsibilities, a new bio-governance model, and an improved inventory system.

The CDC and the Department of Transportation (DOT) conducted an inspection of the LLNL Select Agent Program in February 2006 in response to this shipping incident. The inspection noted improvements in the management of select agents that were made to address the root causes of the shipping incident. Following the inspections, CDC approved the resumption of select agent transfers to and from LLNL and re-authorized the select agent program at LLNL for an additional 3 years.

The Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) assumed lead responsibility for enforcement of the Select Agent and Department of Transportation Regulations. In a January, 2007 letter, OIG alleged that during these shipments, LLNL violated the transfer requirements of the select agent regulations by failing to comply with the applicable shipping and packaging laws when transferring a select agent. In addition, the OIG also alleged that LLNL failed to comply with security and access requirements by allowing an individual not authorized to have access to select agents to package the shipments of anthrax, and that LLNL's Responsible Official (RO) failed to ensure compliance with the shipping and packaging requirements of the select agent regulations. The individual had been authorized to package shipments before, but this authorization had lapsed and the RO had not requested a reinstatement of her registration prior to this shipment. The Regents of the University of California (UC) agreed to resolve its liability for these alleged violations through a settlement agreement. Under the terms of the agreement, UC agreed to pay the OIG $450,000 to resolve these allegations.

Accidents due to transportation of microorganisms are not expected to increase due to the Proposed Action. The addition of milliliter-quantity samples shipped to and from the BSL-3 facility through federal or by commercial or private courier would not be expected to change the overall incidence of risk of transportation accidents. Samples could consist of cells in media contained within DOT-certified packages. The consequences of such accidents would be anticipated to be minor, based on the historical data.

4.3 Analysis of Threat of Terrorist Activity

Environmental reviews prepared under CEQ implementing regulations and DOE NEPA regulations require a presentation of the environmental impacts of the proposed action and the alternatives in comparative form, thus defining the issues and providing a clear basis for choice among options by the decision-maker. With regard to intentional malicious acts, the assessment should compare potential impacts of acts by a terrorist that could derive from the proposed action, or that could occur with significantly greater probability as a result of the proposed action, to the potential impacts from those that could already occur if research with pathogenic agents requiring BSL-3 level containment is not conducted at LLNL (the "No Action" alternative).

Intentional malevolent acts, such as terrorist acts, do not lend themselves to the type of probability analysis conducted in NEPA documents for accidents (DOE 2002a). For a typical NEPA accident analysis, one would attempt to estimate the likelihood of a particular accident

scenario. If it was high enough to warrant concern, one would then consider the potential consequences and analyze them accordingly. Probabilities for accidents and catastrophic events can often be estimated by studying historical data of similar events. For malevolent acts, probability data is generally unavailable, since in addition to technical feasibility, one would also need to devise a means for assessing and quantifying as a weighting factor the willful intent of a purpose-driven individual or group. Such factors are not subject to estimation, and are likely to vary over time.

Therefore in dealing with the potential for terrorism and its NEPA implications, NNSA has adopted an approach based on that which is used in designing security systems and protective strategies, where one begins with the assumption that a terrorist act will occur, regardless of the actual probability of such an act. Increasing levels of protective strategies are then put into place to reduce the risk of a successful terrorist attack to an acceptable level, and subsequently the potential for the facility to be an attractive target for terrorism. The conclusions of the NNSA in the analysis that follows reflect the influence of that approach.

There is a broad range in malevolent and terrorist act scenarios that have been considered and taken into account in planning the design and operation of this facility. Malevolent acts centered on the facility could be perpetrated by a terrorist who has no other intent and no legitimate connection to the facility, but also by other individuals, including a knowledgeable insider. One could postulate that catastrophic damage to the facility could be accomplished either by air or ground attack or by an individual gaining direct access to the building. Similarly, one could postulate other acts of terrorism such as the covert theft of a sample of pathogenic material, so as to avoid immediate detection or discovery which would activate corrective measures and defeat the motives and intent of the terrorist. Research conducted in the proposed facility would be specifically directed to developing technologies and systems to improve national defense against, and mitigate the consequences of these, and other similar terrorist acts.

As discussed below, because of the safeguards and security measures to be taken, NNSA considers the probability of a successful terrorist act at the LLNL BSL-3 Facility would be extremely low and is not expected during the life of the facility. However, potential impacts of acts by terrorists at the LLNL BSL-3 facility were evaluated. Three types of threats were considered:

1) facility damage or destruction from direct terrorist attacks that results in loss of containment;
2) the theft and subsequent release of a pathogenic material by a terrorist from outside LLNL; and
3) the covert theft and subsequent release of a pathogenic material by an insider with access to the facility.

Each of these scenarios are evaluated and the measures NNSA would implement to counter these threats are described. The potential impacts of these three scenarios were evaluated, including the potential impact that a successful terrorist attack would have.

NNSA believes the probability of a successful terrorist act at the LLNL BSL-3 Facility is very low, and it is not an event expected during the life of the facility. In addition, the Research that

would be conducted in the facility would be directed to developing technologies and systems to improve national defense against bio-warfare and bio-terrorism, and thus increase the nation's ability to mitigate the consequences of terrorist acts in the future.

4.3.1 Facility Damage or Destruction from Terrorist Attacks that Result in Loss of Containment

Deliberate facility damage with the intention of releasing small tube-stored samples or working cultures of pathogenic agents would be possible if an individual were able to gain direct access to the facility or cause a catastrophic breach of all containment systems. For example, a suicidal plane crash could breach the facility's containment. Similarly, an explosive device delivered by a vehicle or an individual on foot could breach facility containment. Depending on the time of day and the type of research underway, a loss of containment could result in a release of pathogenic materials. It is probable that the organic biological material would be destroyed by any resulting fire (DOE 2002b). These types of scenarios at the Livermore Main Site would not be possible under the No Action Alternative as the facility would not exist, and are therefore scenarios unique to the proposed NNSA action.

Impacts of a Release Following Loss of Containment. Catastrophic events such as fire, explosions, and airplane crashes, normally considered as initiating events in NNSA radiological or chemical accidents, have the potential to actually reduce the consequences of microbiological material releases due to the heat produced by these events (DOE 2002b). As discussed below, the consequences of a malicious act designed to breach containment are bounded by the accidents and natural catastrophic events evaluated in the EA because they would result in a similar loss of containment.

During routine operations, very limited quantities of biological agents (such as *C. burnetii*) would be in use, usually only enough to begin cultures in petri dishes. Biological agents would typically be handled in a liquid- or solid -medium container, such as a petri dish or flask, which would release very few organisms to the air if spilled. As noted in Section 4.2.2.1, a few operations or activities could hypothetically place up to 1 liter quantities of a slurry of material containing pathogenic organisms at risk at any point in time. One liter of *C. burnetii* generated in tissue culture would contain a maximum of about 1 trillion bacteria. The remaining material would be stored in freezers. An explosion with a subsequent fire would result in a lower risk than without a fire because much of the biological material available for release would likely burn or be killed by heat rather than released to the environment (DOE 2002b). Breach of containment in the absence of an explosion is likely to rupture containers of disinfectant, such as bleach, which would also reduce the amount of viable agent expected to escape the facility following the attack. Additionally, exposure to several environmental factors could kill many airborne microbes in their vegetative state. These factors include ultraviolet light and dehydration. Together, these factors would account for a substantial reduction in the number of microorganisms released, generally within minutes. Therefore, a terrorist act, such as a plane crash, would not be expected to result in a release of greater magnitude than from other catastrophic events already considered in this document or, for example, from releases that routinely occur during lambing season at numerous local ranches, or from births of other infected

domestic or wild animals. By way of comparison, one placenta from a ewe infected with *C. burnetii* contains about 10^{15} organisms (Welsh et al, 1951).

Risk Group 2 and Risk Group 3 agents proposed for use in the facility cause human diseases for which preventive or therapeutic interventions may be available. Nationally, health care providers have been trained to recognize symptoms of exposures to Risk Group 2 agents (such as anthrax) and Risk Group 3 agents. Local hospitals and health care providers in the Livermore area have been briefed by LLNL medical staff. For agents studied in the BSL-3 facility, prophylactic measures are available in the event of exposure. Individuals could be inoculated to prevent infection or treated to recover from exposure to a known biological agent, just as presently is done in medical facilities across the country when these same biological organisms from natural sources infect members of the general public. There have been a number of reported cases (in 4 selected years) of Q-Fever (18), Tularemia (10), and Plague (3), and other select-agent diseases, from natural and accidental exposures in California (see Table 3-2). Only one death (from Q-Fever) was reported within this group of select-agent diseases. These statistics reflect the widespread availability of diagnostic testing and treatments procedures for typical Risk Group-2 and -3 select agents in case of exposure and infection.

In general, considering the current levels of security awareness and response available, it is probable that if a successful terrorist attack on the facility resulted in the release of a biological agent to the environment, the effects of such a release would be localized in time (hours immediately following the terrorist act) and place (downwind from the BSL-3 facility). As noted, exposed individuals could be inoculated to prevent infection or treated to assist in recovery. For example, studies (DA 1989) reported that if a non-immunized person were exposed to defined aerosols of up to 150,000 pathogenic doses of virulent *C. burnetii*, the disease could be avoided by giving one milliliter of vaccine within 24 hours after exposure and by instituting antibiotic therapy.

Security Measures to Counter Direct Attacks. It is not possible to accurately predict the probability of intentional attacks at LLNL or at other critical facilities, or the nature of these attacks. The number of scenarios is large, and the likelihood of any type of attack is unknowable (DOE 2002a). Nevertheless, in the aftermath of the attacks of September 11, 2001, NNSA reevaluated scenarios involving malevolent, terrorist, or intentionally destructive acts at LLNL in an effort to identify potential security vulnerabilities and assess possible improvements to security procedures and response measures. Security is a critical priority at DOE facilities, and DOE continues to identify and implement measures designed to defend against and deter attacks at its facilities. Substantive details of terrorist attack scenarios and security countermeasures are classified, because disclosure of this information could be exploited by terrorists to plan attacks.

The requirements for possession, use, and transfer of Select Agents (SAs) and toxins in the United States are established in 42 CFR Part 73. Section 73.11 requires facilities subject to the regulations to develop and implement a security plan establishing policies and procedures that ensure the security of areas containing SAs and toxins based on a risk assessment. A risk methodology, agreed to by the University of California /NNSA/Sandia National Laboratories/Department of Energy Risk and Threat Assessment Methodology Working Group,

guides the development of security risk and threat assessments as they relate to LLNL operations. This methodology is still being used under the new LLNL M&O contractor.

The *Biological Risk and Threat Assessment* (BRTA) (LLNL 2005) developed for the BSL-3 facility at LLNL follows the methodology established by the Working Group and uses the DOE Design Basis Threat[27] to examine the potential vulnerabilities of the facility and its operations, and to mitigate risks. The BRTA is an in-depth analysis that focused on the Design Basis Threat and other potential scenarios, such as acts by terrorists or violent activists.[28] The *LLNL Select Agents and Toxins Security Plan* (LLNL 2006) is based on the BRTA and provides an integrated safeguards and security management approach to implementing a protection program for LLNL's SA and toxin use and storage areas in conformance with the SA requirements of 42 CFR Part 73. In addition to general security programs at the LLNL main site, this program encompasses both physical and personnel security aspects as described below.

When compared with other facilities and locations in the environment for which pathogenic agents could be obtained, the LLNL BSL-3 facility is one of the most physically secure against such efforts. Part 73 outlines minimum security requirements for possession and use of select agents and toxins. The key requirements are locking refrigerators and freezers to store select agents, and controlling access to areas where select agents and toxins are stored or used from the public areas of the building.

Several aspects of the layered physical security systems at LLNL exceed the security requirements imposed by Part 73 on similar facilities. There are over 1350 of these facilities nationwide; the majority of which are either academic or clinical/diagnostic facilities (GAO 2007). First, the LLNL site is surrounded by a patrolled security fence with badge-identification required for entry. The LLNL Protective Force Division provides numerous types of protection, including perimeter access control, fixed access and surveillance points, random vehicle patrols, and an armed response force. The Protective Force Division conducts periodic drills and training to maintain its effectiveness. In March 2004, DOE's Office of Safeguards and Security Evaluations completed a comprehensive review of LLNL security programs and rated the protective force operations as "Effective Performance," which is the highest rating possible.

Building 368 is inside the LLNL protected perimeter. In addition, access to Building 368 is controlled by badge identification and limited to employees registered with CDC for work with select agents, authorized by LLNL management, and enrolled in the Select Agent Human Reliability Program. (This program is discussed in Section 4.3.3) Access to individual laboratories is further controlled by an additional personal identification system to only those staff members approved for work during specific shifts. Building and laboratory access are continuously monitored. Finally, all points of access to the facility, including foundation and HVAC access point, have been physically secured against unauthorized entry. Motion detectors have also been installed in the laboratories and mechanical rooms. Within the facility's laboratories, all select agents are kept in locked freezers when not in use.

[27] The Design Basis Threat identifies credible threats that are postulated for the purpose of analyzing security programs, systems, components, equipment, information, or material.
[28] A violent activist is defined in the Design Basis Threat as an individual who commits violent acts out of opposition to Department programs for ideological or other reasons.

4.3.2 Theft and Subsequent Release of a Pathogenic Material by a Terrorist from outside LLNL

The CDC defines a bioterrorism attack as "the deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death in people, animals, or plants." The CDC recognizes that terrorists may consider using biological agents because they can be extremely difficult to detect and some may not cause illness immediately. The CDC separates bioterrorism agents into three categories depending on how easily they can be spread and the severity of effects they cause. "Category A" agents are considered the highest risk. These agents include organisms or toxins that pose the highest risk because:

- they can be easily spread or transmitted from person to person;
- they result in high death rates and have the potential for major public health impacts;
- they might cause panic and social disruption; and
- they require special actions for public health preparedness.

As noted in other sections of this EA, several Risk Group-2 and Risk Group-3 organisms which may be handled and stored in the BSL-3 facility at LLNL are Category A agents (See Appendix A.3, Table A-1). These agents are routinely handled and stored at over 250 BSL-3 facilities in the United States, and in hospitals that specialize in infectious disease treatment.

Evaluation of the potential terrorist threat that could result from the presence of pathogenic agents in the BSL-3 facility is fundamentally different from that associated with threats to nuclear materials and other hazardous materials at a nuclear facility. As opposed to materials such as spent nuclear fuel rods or special nuclear material, pathogenic agents studied in a BSL-3 facility are usually zoonotic organisms that are present in many locations and occur widely in domestic and wild animal stocks. As such, these agents are already obtainable from the environment. For instance, anthrax (*B. anthracis*, a Risk Group 2 agent) can be found near certain sheep raising operations. The organism causing Q fever, *Coxiella burnetii*, (a Risk Group 3 agent requiring BSL-3- level protection and handling procedures) also occurs in livestock animals. Coxiella burnetti organisms are found in huge numbers in birth fluids, especially amniotic fluid, placenta (up to 10^{12}/g), and fetal membranes of parturient ewes, goats, or cows (Stocker, 1955). Valley Fever in is commonly contracted in California as a result of breathing airborne dust containing *Coccidioides immitis,* a Risk Group 3 fungus readily found in soil throughout most of the Central Valley. Hantavirus is can be found in disused buildings containing wild mice feces. Plague is caused by *Yersinia pestis*, which is endemic in rodent populations throughout the Sierra Nevada mountains. The organism that causes rabbit fever, *Francisella tularensis*, derives its name from Tulare County, just one of the counties in California where the organism is prevalent. Thus, a knowledgeable terrorist could collect environmental samples of many Risk Group-2 or Risk Group-3 microorganisms and grow large quantities of them for dissemination without attacking or stealing from a government or private BSL-3 facility. This is clearly different than the analogous risk to the security of high-level radioactive spent fuel rods at a nuclear power plant, as those "source materials" are uniquely concentrated radioisotopes that are not readily obtainable or producible and cannot be "grown" to larger volume from a minute sample.

The most serious ultimate potential impacts of a terrorist act using material stolen from the LLNL BSL-3 facility would be similar to those that could occur should a terrorist collect the same organisms from infected livestock, wild animals or the locations in the environment where they occur naturally. Because these and other pathogenic organisms to be studied in the proposed BSL-3 facility are typically collected from environmental samples in the first place, they are just as accessible to a technically-competent terrorist (or group) as to any legitimate researcher. As such, the proposed action does not measurably add to the avenues already available to a terrorist for obtaining pathogenic materials or measurably increase the likelihood of this type of malicious act. Therefore, the facility is not considered an attractive target for an outside terrorist. Because a malicious individual could already obtain pathogenic material by other methods under the No-Action ("status quo") Alternative, the presence of pathogenic agents in the proposed, highly secured BSL-3 facility would not pose any new or greater risk to human health or the environment from an outside terrorist or terrorists than already accrues without operation of the BSL-3 facility at LLNL.

4.3.3 Covert Theft and Subsequent Release of a Pathogenic Material by an Insider with Access to the Facility

Although not expected to occur due to stringent personnel security and screening programs at LLNL, surreptitious removal of a small vial containing a few milligrams of a select agent, or material swabbed from a vial, could be accomplished by a motivated, technically competent insider with access to the locked storage freezers. Following theft, five essential steps need to be accomplished in order to cause large numbers of human health impacts using the stolen organism:

One must obtain the appropriate strain of the pathogen;
One must know how to handle the organism;
One must know how to grow it in a way that will produce the appropriate characteristics;
One must know how to store the culture and to produce sufficiently large quantities; and
One must know how to prepare and disperse the agent properly.

In addition, the material must be managed in a way that maintains the virulence or infectivity during production, storage, transportation and dispersion. Accomplishing these requirements was difficult even for long-term and well-funded programs in the former Soviet Union and other state-run programs.

Once offsite, the initial stolen swab or sample could be cultured to increase the amount available for use in an attack against the public. As noted above, refining the cultured product to obtain a highly dispersible form of the select agent requires a high degree of technical skill and specialized equipment. However, a dispersible form of *B. anthracis* was distributed through the U.S. Postal Service in 2001. As a result of this attack, 22 people were infected and 5 people died. Assuming a highly technically competent individual (or group) was successful in obtaining pathogenic material, and given general constraints such as access and use of a single biosafety cabinet in a general laboratory setting, it might be possible to grow quantities of dispersible *B. anthracis* similar to those released in 2001 (although it has never been officially confirmed, the New York Times reported in 2002 that the amount in one of the 4 letters was 0.871 grams

[Broad and Johnston, 2002]). This material could then be distributed through the U. S. Postal Service in local major cities such as Oakland or San Francisco to the public or elected officials.

Impacts of a Theft and Subsequent Release of a Pathogenic Material. As shown in 2001, dramatic human health impacts and economic disruption can result following the release of pathogenic materials. If a terrorist was able to obtain material from any source, refine the material to a dispersible form, and then disperse it through mechanisms such as the postal service. One could assume that tens of people could be infected and a few unsuspecting or untreated people might die. However, limitless other scenarios could be postulated involving greater amounts, different agents and different pathways such as air, water or food. Some scenarios could have greater consequences (e.g., use of larger quantities), and some of which would have lesser consequences (e.g., agent dilution and partial or complete destruction upon release to air, water, or food environments as the transport mechanism). Taken to extremes, one can even postulate scenarios with catastrophic implications. (SNL/LLNL, 2006)

Since the 2001 letter attacks, emergency response systems have been put into place to respond to a release of biological agents in the U.S. Postal Service and other means that might be used for dispersal. The Postal Service has implemented anthrax-related engineering controls and work practices that reduce the potential for an undetected re-aerosolization event. In other areas, BioWatch, a system designed to detect and locate an aerosol release of a bio-threat organism quickly and accurately enough for an effective response, is now deployed in major cities nationwide under the auspices of the U.S. Department of Homeland Security (DHS). BioWatch laboratories, including LLNL, are part of the Laboratory Response Network operated by the CDC. The continuing LLNL research support to these already-vital National Security programs/systems is one of the reasons the DOE BSL-3 facility at LLNL was proposed; it is considered essential to national defense programs administered by DHS.

Personnel and Inventory Security Measures to Counter Theft of Pathogenic Materials. In addition to physical security measures described above, and as specified in 42 CFR Part 73, persons possessing, using, or transferring select agents and toxins must first:

- successfully pass the Department of Justice Security Risk Assessment;
- be authorized by the HHS Secretary or APHIS administrator; and
- be registered with the CDC.

In addition to these federal requirements, UC also requires that personnel having access to select agents and toxins must enroll in and be approved by the LLNL Select Agent Human Reliability Program (SAHRP). SAHRP is a security reliability program that selects, trains, certifies, and monitors individuals whose work requires unescorted access to select agents and toxins. Personnel in the SAHRP are screened for physical, mental and personality disorders potentially affecting their judgment and reliability, alcohol abuse, use of illegal drugs or the abuse of legal drugs or other substances, or any other condition or circumstances that may be a security concern. In addition to SAHRP approval, personnel must be verified by Laboratory management and approved by the Responsible Official (RO) as having received the appropriate education, training, and experience for access to select agents. (As by 42 CFR Part 73, the RO is the person charged with ensuring compliance with the applicable regulations.) Access to select agents in the BSL-3 facility would be limited to a very small number (generally less than 10) of qualified and cleared employees.

CDC regulations require extensive documentation of activities involving select agents. Only personnel on LLNL's CDC registration are allowed to handle the agents. All access to select agent handling areas would be recorded. Records would be kept every time an individual enters or leaves an area with select agent samples, regardless of how brief a time or how often they do so. Freezers will have logs to record access, transfer, and use of the stored select agents. To satisfy the requirements of 42 CFR Part 73, LLNL's Responsible Official (RO) must ensure that detailed records of information necessary to give a complete accounting of all activities related to select agents or toxins access and operations are maintained. The RO reviews the inventory at least annually.

4.3.4 Overall Risk Assessment

The M & O contract for LLNL, DOE directives, and federal law require that LLNL protect the laboratory and the public against a broad range of terrorist threats and other hostile acts that may cause unacceptable impacts on national security or on the health and safety of employees, the public, or the environment. A multi-level security strategy is used, with measures applied site-wide and at the facility and personnel levels.

Across the site, extensive security measures are in place to detect and repel intrusions consistent with LLNL's mission as a nuclear weapons laboratory. The Biological Risk and Threat Assessment developed for the BSL-3 facility examined the potential vulnerabilities of the facility and its planned operations, and identified additional measures to mitigate risks. This assessment guided the development and implementation of multi-layered and robust security programs

specifically designed to mitigate threats to select agents at the facility. Personnel security policies and practices have been implemented for work with pathogenic agents at LLNL. By denying access to insiders whose backgrounds suggest they are at risk for engaging in unreliable, untrustworthy, or disloyal behavior, these measures provide an additional safeguard against the loss of pathogenic materials.

When these measures are considered together, the probability of a successful terrorist attack at the LLNL BSL-3 facility has been minimized to an extent commensurate with the potential threat. A direct assault of the facility is highly unlikely to succeed, and would have impacts bounded by the catastrophic events already evaluated in Section 4.2. Because pathogenic agents are already available in nature and at other, less secure locations, the risk of an outside terrorist acquiring pathogenic material is not significantly increased by having pathogenic material at LLNL (one of the most secure facilities in the nation). And while the theft of pathogenic materials by an insider from any bio research facility could have very serious consequences, this scenario is not expected to occur at LLNL due to human reliability programs, security procedures, and management controls at the facility and the laboratory.

NNSA believes that the potential for terrorist activity targeting the proposed BSL-3 facility does not result in measurable impacts to human health or the environment. As stated in section 1.3, operation of the facility would support NNSA's mission to "develop, demonstrate and deliver technologies and systems to improve domestic defense capabilities and, ultimately, to save lives in the event of a chemical or biological attack." The work that would be conducted in the biodefense field at the BSL-3 facility would focus on providing both the basic bioscience and the tools necessary to present bioterrorism. Work would be conducted on topics such as detection of biowarfare threats, human and microbial forensics research and applications, and presymptomatic disease detection. LLNL could use this information to develop advanced detection systems to provide early warning, identify populations at risk and contaminated areas, and facilitate prompt treatment. Researchers at the facility would attempt to develop DNA signatures and biological forensics technologies to identify infectious agents, their geographical origin, and initial sources of infection. Similar approaches are applied to human forensics, and are used in both law enforcement and intelligence-gathering activities.

4.4 REMODEL/UPGRADE ALTERNATIVE

Construction: This alternative would mainly be disruptive to the other workers in the building being remodeled or upgraded. The first step would be deconstruction of the identified laboratory. The laboratory room would first be stripped to the bare walls, floor and ceiling. Ducting, plumbing and electrical work would be done next, then new walls would be installed that could be made seamless. This work would be noisy, but periodic exceedance of the OSHA standard would be infrequent, depending upon the specific task. This activity could interrupt research in adjacent laboratories due to the additional dust, vibration, and the effect on electrical or "plumbed" service being periodically shut off. The most difficult task would be air-balancing of the BSC and the effects of activities in the adjacent laboratories.

Operations. The effects of operation would be the same as for the Proposed Action.

Decontamination and Decommissioning. The effects of D&D would be the same as for the Proposed Action.

4.5 CONSTRUCT ON-SITE ALTERNATIVE

Site Preparation and Construction. The difference between this alternative and the Proposed Action is the time it would take to construct the facility at the proposed LLNL site. This alternative would mainly be more disruptive to workers in the adjacent buildings for a longer time (many months).

Operations. The effects of operation would be the same as for the Proposed Action.

Decontamination and Decommissioning. The effects of D&D would be the same as for the Proposed Action.

4.6 ENVIRONMENTAL CONSEQUENCES OF THE NO ACTION ALTERNATIVE

Under this alternative, LLNL would continue contracting with other laboratories for services or laboratory space for the work proposed for the BSL-3 laboratory. This would represent no change in the level of operations at LLNL, even though mission requirements can be expected to continue to grow. There would be no change from the current conditions with respect to human health, ecological resources, transportation, waste management, utilities and infrastructure, noise, geology, soils, seismicity, visual resources, or air quality.

While not considered a "resource area" for analysis of impacts, continuing problems with the quality and security of data produced by outside laboratories could adversely affect the ability of LLNL to conduct high-quality, efficient research on BSL-3 organisms and may additionally adversely affect NNSA's security mission capabilities.

5.0 CUMULATIVE EFFECTS

Cumulative effects on the environment result from the incremental effect of an action when added to other past, present, and reasonably foreseeable future actions, regardless of what agency or person undertakes them. These effects can result from individually minor, but collectively significant, actions taking place over a period of time (40 CFR 1508.7). This section considers the cumulative effects resulting from the implementation of the Proposed Action and reasonably foreseeable future actions in the Building 360 Complex Area and adjacent lands.

Readers of this document should note that since this EA was originally issued, DOE has issued the *Final Site-wide Environmental Impact Statement for Continued Operation of Lawrence Livermore National Laboratory and Supplemental Stockpile Stewardship and Management Programmatic Environmental Impact Statement* (SWEIS, DOE/EIS-0348, DOE/EIS-0236-S3, DOE 2005). This document contains an extensive discussion of the cumulative effects of LLNL operations, which includes this facility.

LLNL Operations at the Building 360 Complex Area. No new types of operations and very few, if any, new personnel would be introduced into LLNL as a result of the Proposed Action. Land use within the Building 360 Complex Area would remain unchanged. Local traffic congestion would be unaffected by the Proposed Action since there would be no net increase expected in the number of workers for the Complex Area.

Due to the small size of the proposed facility the projected quantities of water, wastewater, and energy consumption would be insignificant relative to that used by LLNL. All workers in the proposed facility would likely be relocated from adjacent buildings and the net increases due to the new facility in these areas would be expected to be very minor.

Parking availability in the Building 360 Complex Area would change from the current configuration due to the effects of removal of parking spaces to erect the proposed new facility. However, since adjacent parking lots are existing and readily available, the Proposed Action would not significantly alter the general employee parking space availability at LLNL.

The overall visual quality within the Building 360 Complex Area would not change significantly because the new construction is in the middle of and directly adjacent to several older buildings. The minor negative effects on viewsheds of LLNL-area development and the slightly increased lighting in the night sky would be considered a minor regional effect. The Proposed Action is not expected to be a major contributor to this effect; the building would be one-story and would therefore not be visible above the building outlines of nearby structures. Additionally, the parking area and the BSL-3 facility would require little nighttime lighting and those lights required would be designed to shine downward toward the parking lot and ground surfaces.

Implementing the Proposed Action would generate noise primarily during the daytime hours during initial construction activities and during D&D. This noise generation would be mostly confined to the immediate Building 360 Complex Area and would be mostly heard only by the involved workers.

Alameda County, the City of Livermore, and LLNL have historically been in a non-attainment area for air quality with regards to criteria pollutants; but, visibility has always been excellent. Implementation of the Proposed Action is expected to have an insignificant impact on the overall air quality of the valley.

As stated in Table 3-1 (Section 3.2), there would be no Environmental Justice issues associated with the proposed facility since there would be no disproportionately higher adverse human health or environmental effects on low income or minority populations.

6.0 AGENCIES AND PERSONS CONSULTED

In the process of preparing material for this EA, DOE had discussions with various federal agencies and organizations including the CDC, NIH, General Services Agency (GSA), U.S. Department of the Army (DA), Utah Department of Environmental Quality, Colorado State University, and Lawrence Livermore National Laboratory. These contacts were made to gain an understanding about their respective experiences with BSL-3 laboratories and the operational and accident history of their own operations.

No project-specific consultation with the U.S. Fish and Wildlife Service was conducted in compliance with the *Endangered Species Act (ESA)*, as the Proposed Action and alternatives would not be expected to affect either individuals of threatened or endangered species or their critical habitat. Recent sitewide consultations under Section 7 of the ESA were conducted by the DOE in 1997 and 1998 concerning maintenance activities at LLNL. No consultation with the State Historic Preservation Office was conducted in compliance with the *National Historic Preservation Act* (16 U.S.C. § 470, 36 CFR 800.5), as the Proposed Action and alternatives would not be expected to affect any cultural resource.

7.0 REFERENCES

7 CFR 330: Title 7 U.S. Code of Federal Regulations Part 330, "Agriculture, Chapter III – Animal and Plant Health Inspection Service, Department of Agriculture, Federal plant and pest regulations; general; plant pests; soil; stone, and quarry products; garbage," Washington, DC (January 1, 2001).

7 U.S.C. § 2131-2157: Title 7 U.S. Code Section 2131-2157, "Animal Welfare Act," as Amended.

9 CFR 92: Title 9 U.S. Code of Federal Regulations Parts 92, 94, 95, 96, 122, and 130, "Animals and Animal Products, Chapter I – Animal and Plant Health Inspection Service, Department of Agriculture," Washington, DC (January 1, 2001).

10 CFR 1021: Title 10 U.S. Code of Federal Regulations, U.S. Department of Energy, "National Environmental Policy Act Implementing Procedures, "Washington, DC (January 1, 1999).

15 CFR 730: Title 15 U.S. Code of Federal Regulations Parts 730-799, "Regulations Relating to Commerce and Foreign Trade, Chapter VII – Bureau of Export Administration, Department of Commerce," Washington, DC (January 1, 2001).

16 U.S.C. § 430: Title 16 U.S. Code Section 430, "American Antiquities Act," as Amended.

16 U.S.C. § 470: Title 16 U.S. Code Section 470, "National Historical Preservation Act," as Amended (and 36 CFR 800.5).

29 CFR 1910.1030: Title 29 U.S. Code of Federal Regulations Part 1910, Section 1030, "Bloodborne Pathogens," Washington, DC, with amendments as of (January 1, 2001).

29 CFR 1910.12: Title 29 U.S. Code of Federal Regulations Part 1910, Section 12, "Construction Work," Washington, DC, with amendments as of (January 1, 2001).

29 CFR 1910.95: Title 29 U.S. Code of Federal Regulations Part 1910, Section 95, "Occupational Noise Exposure," Washington, DC, with amendments as of (January 1, 2001).

29 CFR 1926: Title 29 U.S. Code of Federal Regulations Part 1926, "Occupational Safety and Health Standards for the Construction Industry," Washington, DC, with amendments as of (January 1, 2001).

29 CFR 1990: Title 29 Code of Federal Regulations Part 1990, "Identification, Classification, and Regulation of Potential Occupational Carcinogens," Washington, DC, with amendments as of (January 1, 2001).

32 CFR 627: Title 32 U.S. Code of Federal Regulations Part 627, U.S. Department of the Army, "The Biological Defense Safety Program, Technical Safety Requirements (DA Pamphlet 385-69)," Washington, DC (July 1, 2000).

36 CFR 800.5: Title 36 U.S. Code of Federal Regulations Part 800.5, National Archives and Records Administration, "Parks, Forests, and Public Property" Chapter VIII, "Advisory Council on Historic Preservation," Washington, DC (January 1, 1998).

39 CFR 111: Title 39 U.S. Code of Federal Regulations Part 111, U.S. Postal Service, "General Information on Postal Service," and incorporation by reference the *Domestic Mail Manual*, Washington, DC (July 1, 2000).

40 CFR 9: Title 40 U.S. Code of Federal Regulations Part 9, U.S. Environmental Protection Agency, "OMB Approvals Under the Paperwork Reduction Act," Washington, DC.

40 CFR 141-142: Title 40 U.S. Code of Federal Regulations Parts 141-142, U.S. Environmental Protection Agency, "National Primary Drinking Water Regulations" and "National Primary Drinking Water Regulations Implementation," Washington, DC.

40 CFR 261: Title 40 U.S. Code of Federal Regulations Parts 261 through 272, U.S. Environmental Protection Agency, "Resource Conservation and Recovery Act," Washington, DC (1976).

40 CFR 300: Title 40 U.S. Code of Federal Regulations Parts 300, U.S. Environmental Protection Agency, "Comprehensive Environmental Response, Compensation, and Liability Act," Washington, DC (1980).

40 CFR 350: Title 40 U.S. Code of Federal Regulations Parts 350, 355, 370, and 372, U.S. Environmental Protection Agency, "Emergency Planning and Community Right-to-Know," Washington, DC (October 17, 1986).

40 CFR 403: Title 40 U.S. Code of Federal Regulations Part 403, U.S., Environmental Protection Agency, "Federal Water Pollution Control Act of 1972," Washington, DC.

40 CFR 1500-1508: Title 40 U.S. Code of Federal Regulations, Council on Environmental Quality, Executive Office of the President, "Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act," (Reprint 1992).

42 CFR 71: Title 42 U.S. Code of Federal Regulations Part 71, "Foreign Quarantine," Washington, DC (October 1, 2000).

42 CFR 72: Title 42 U.S. Code of Federal Regulations Part 72, "Interstate Shipment of Etiologic Agents," Washington, DC (October 1, 2000).

42 CFR 73: Title 42 U.S. Code of Federal Regulations Part 73, "Possession, Use, and Transfer of Select Agents and Toxins," Washington, DC (March 18, 2005).

49 CFR 171: Title 49 U.S. Code of Federal Regulations Part 171, "Chapter I – Research and Special Programs Administration, Department of Transportation, Part 171 – General Information, Regulations, and Definitions," (October 1, 2000).

49 CFR 171-178: Title 49 U.S. Federal Register Parts 171-178, "Part VI - Department of Transportation; Research and Special Programs Administration; Hazardous Materials: Revision to Standards for Infectious Substances and Genetically Modified Micro-Organisms; Proposed Rule," (Monday, January 22, 2001).

49 CFR 172: Title 49 U.S. Code of Federal Regulations Part 172, "Chapter I – Research and Special Programs Administration, Department of Transportation, Part 172 – Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, and Training Requirements," (October 1, 2000).

49 CFR 173: Title 49 U.S. Code of Federal Regulations Part 173, "Chapter I – Research and Special Programs Administration, Department of Transportation, Part 173 – Shippers – General Requirements for Shipments and Packagings," (October 1, 2000).

49 CFR 178: Title 49 U.S. Code of Federal Regulations Part 178, "Chapter I – Research and Special Programs Administration, Department of Transportation, Part 178 – Specifications for Packagings," (October 1, 2000).

50 CFR 17.11: Title 50 U.S. Code of Federal Regulations Part 17.11, U.S. Fish and Wildlife Service, Department of Interior, "Endangered and Threatened Wildlife and Plants," Washington, DC (October 1, 2000)

50 U.S.C. § 2301: Title 50 U.S. Code Sections 2301-2367, "War and National Defense, Chapter 40, Defense Against Weapons of Mass Destruction."

50 U.S.C. § 2401: Title 50 U.S. Code Section 2401, "Establishment and Mission," Cornell Legal Information Institute (LII), http://www4.law.cornell.edu/uscode/unframed/50/2401.html, (downloaded June 2001).

50 U.S.C. § 2402: Title 50 U.S. Code Section 2402, "Administrator for Nuclear Security," Cornell Legal Information Institute (LII), http://www4.law.cornell.edu/uscode/unframed/50/2402.html.

ABSA 1998: American Biological Safety Association, "Risk Group Classification for Infectious Agents," Revision 1.0 from ABSA website http://www.absa.org/riskgroups/ (downloaded March 14, 2001).

ACGIH 2000: American Conference of Governmental Industrial Hygienists (ACGIH), "2000 TLV's and BEIs; Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices," Cincinnati, OH, pages 112-114 ACGIH (2000).

ANSI 1983: American National Standards Institute, "Specifications for Sound Level Meters," ANSI S1.4-1983 (1983).

ANSI 1998: American National Standards Institute, "Accessible and Usable Buildings and Facilities," ANSI A177.1-1998 (February 13, 1998).

Association of Bay Area Governments 2001: Association of Bay Area Governments, *Projections 2002, Forecasts for the San Francisco Bay Area to the Year 2025,* Association of Bay Area Governments, San Francisco, CA, December 2001.

Bascom 1996: Rebecca Bascom, MD, MPH, University of Maryland, "Occupational Health Programs," Proceedings of the 4th National Symposium on Biosafety, "Working Safety with Research Animals," Atlanta, GA (January 27-31, 1996)

Benenson 1959: Abram. S. Benenson, "Q fever vaccine: efficacy and present status; Medical Science Publication No. 6, Symposium on Q Fever," AGO 10047B, Superintendent of Documents, U.S. Government Printing Office, Washington, DC (1959).

Benenson 1995: Abram S. Benenson Editor, "Control of Communicable Diseases Manual," American Public Health Association, Sixteenth Edition (1995).

BLS 2001: U.S. Bureau of Labor Statistics, "Safety and Health Statistics," available on-line at http://stats.bls.gov/blshome.htm.

BMI 1993: Battelle Memorial Institute "Environmental Assessment for the BL-3 Laboratory at Battelle's Medical Research and Evaluation Facility," West Jefferson, OH (June 1993).

BPHC 2005: Barry, M. Anita, "Report of Pneumonic Tularemia in Three Boston University Researchers, November 2004 – March 2005," Boston Public Health Commission, Boston, Massachusetts (March 2005).

Broad and Johnston 2002: W. Broad and D. Johnston, "Anthrax Sent Through Mail Gained Potency by the Letter", New York Times, May 7, 2002

Burden and Sims 1999: David S. Burden and Judith L. Sims, "Fundamentals of Soils Science as Applicable to Management of Hazardous Wastes," U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response, EPA/540/S-98/500 (April 1999).

BWC 1972: U.S. Department of State, "Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction," http://www.state.gov/www/global/arms/treaties/bwc1.html.

Cantor 1996: L. Cantor, "Environmental Impact Assessment," McGraw Hill, Inc., Second Edition (1996).

CDC 1974: Centers for Disease Control, "Classification of Etiologic Agents on the Basis of Hazard," U.S. Department of Health, Education, and Welfare, Public Health Service, CDC, Fourth Edition (1974).

CDC 1999: Centers for Disease Control and Prevention, "Biosafety in Microbiological and Biomedical Laboratories," U.S. Department of Health and Human Services, Public Health Service, CDC and National Institutes of Health (NIH), Fourth Edition, Washington, DC (April 1999).

CDC 2000a: Centers for Disease Control and Prevention, "Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response; Recommendations of the CDC Strategic Planning Workgroup," U.S. Department of Health and Human Services, CDC, Morbidity and Mortality Weekly Report (MMWR); Recommendations and Reports, Vol. 49, No. RR-4 (April 21, 2000).

CDC 2000b: Centers for Disease Control and Prevention, "Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets," U.S. Department of Health and Human Services, Public Health Service, CDC and NIH, Washington, DC (September 2000).

CDC 2000c: Centers for Disease Control and Prevention, "Laboratory-Acquired Human Glanders – Maryland, May 2000," U.S. Department of Health and Human Services, CDC, Morbidity and Mortality Weekly Report (MMWR), Vol. 49, No. 24 (June 23, 2000).

CDC 2001b: Centers for Disease Control and Prevention, "Q Fever," U.S. Department of Health and Human Services, Public Health Service, Viral and Rickettsial Zoonoses Branch, available on-line at: http://www.cdc.gov/ncidod/dvrd/qfever/index.htm (downloaded July 2, 2001).

CDC 2006, Centers for Disease Control and Prevention (CDC), "Bioterrorism" http://www.bt.cdc.gov/bioterrorism/, accessed December 12, 2006

CDF 2001: California Department of Finance, "California Statistical Abstract: Section E, Health and Welfare; Table E-4 – Cases and Deaths, Selected Notifiable Diseases, California (2001) [available on-line at: http://www.lib.berkeley.edu/PUBL/california.html]

CHS 2005: Constella Health Services, *Final Report, Survey for Determining the Location, Capacity, and Status of Existing and Operating BSL-3 Laboratory Facilities within the United States*, Constella Health Sciences, Center for Health Research, Durham, NC 27713, June 2, 2005.

Cieslak and Eitzen 1999: Theodore J. Cieslak and Edward M. Eitzen Jr., "Clinical and Epidemiologic Principles of Anthrax," Centers for Disease Control and Prevention, Emerging Infectious Diseases, Vol. 5, No. 4, pages 552-555 (July-August 1999).

City of Livermore 2000: City of Livermore, CA, "Livermore Planning and Zoning Code," A Codification of the Planning and Zoning Ordinances of the City of Livermore, CA, Code Publishing Co., Seattle, WA (2000).

City of Livermore and LSA 2002: City of Livermore and LSA Associates, Inc., *General Plan Update,* Livermore, CA, July 23, 2002.

Coker et al. 1998: P.R. Coker, K. L. Smith, and M. E. Hugh-Jones, "Anthrax in the USA," Proceedings of the Third International Conference on Anthrax, Plymouth, England, Vol. 44 (September 7-10, 1998).

Collins 2000: C. H. Collins, "Laboratory – and some other Occupationally-acquired Microbial Diseases: A Bibliography," available on-line at the website of the European Federation Biotechnology, Working Party Safety in Biotechnology at: http://www.boku.ac.at/iam/efb/efb_wp.htm (August 7, 2000).

Collins and Kennedy 1999: C. H. Collins and D. A. Kennedy, "Laboratory-Acquired Infections; History, Incidence, Causes and Prevention," Fourth Edition, Butterworth-Heinemann, Woburn, MA (1999).

DA 1989: Department of the Army, U. S. Army Medical Research and Development Command (USAMRDC), Final Programmatic Environmental Impact Statement; Biological Defense Research Program," Fort Detrick, Frederick, MD (April 1989).

DA 1992: Department of the Army, U.S. Army Dugway Proving Ground, "Final Environmental Impact Statement, Life Sciences Test Facility, Dugway Proving Ground, Utah," Dynamac Corporation, Rockville, MD (March 1992).

DA 1996: Department of the Army, Walter Reed Army Institute of Research, "Environmental Assessment, Biological Defense Research Program at the Armed Forces Institute of Pathology," United States Army Medical Research and Materiel Command, Fort Detrick, Fredrick, MD (April 1996).

DHS 2005: Department of Health and Human Services, *Possession, Use, and Transfer of Select Agents and Toxins*, 42 CFR Parts 72 and 73, March 18, 2005

DOE 1984: U.S. Department of Energy, "Environmental Protection, Safety, and Health Protection Standards," DOE Order 5480.4 (April 15, 1984 with change January 7, 1993).

DOE 1992: U.S. Department of Energy, "Final Environmental Impact Statement and Environmental Impact Report for the Continued Operation of Lawrence Livermore National Laboratory and Sandia National Laboratories, Livermore, August 1992, DOE EIS-0157, U.S. Department of Energy (EIS), Washington, D.C., and University of California (EIR), SCH90030847 (1992).

DOE 1993: U.S. Department of Energy, "Recommendations for the Preparation of Environmental Assessments and Environmental Impact Statements," U.S. Department of Energy, Office of NEPA Oversight, Washington, DC (1993).

DOE 1996a: U.S. Department of Energy, "Facility Safety," DOE Order O 420.1, Washington, DC (October 24, 1996).

DOE 1997: U.S. Department of Energy, "Construction Safety Management Guide for use with DOE ORDER 440.1," U.S. Department of Energy, Office of Worker Health and Safety (DOE –G-4401.-2), Washington DC (June 26, 1997).

DOE 1998: U.S. Department of Energy, "Worker Protection Management for DOE Federal and Contractor Employees," U.S. Department of Energy, Office of Environment, Safety and Health, (DOE O 440.1A), Washington, DC (March 27, 1998).

DOE 1999: U.S. Department of Energy, "Supplement Analysis for Continued Operation of Lawrence Livermore National Laboratory and Sandia National Laboratories, Livermore, March 1999, DOE/EIS-0157-SA-01, U.S. Department of Energy, National Nuclear Security Administration, Oakland Operations Office, Oakland, CA (1999).

DOE 2002a: U.S. Department of Energy, "Recommendations for Analyzing Accidents under the National Environmental Policy Act", July 2002.

DOE 2002b: U.S. Department of Energy, "Environmental Assessment for The Proposed Construction and Operation of a Biosafety Level 3 Facility at Los Alamos National Laboratory, Los Alamos, New Mexico," U.S. Department of Energy, National Nuclear Security Administration, Office of Los Alamos Site Operations, DOE/EA-1364 (February 26, 2002).

DOE 2005: "Final Site-wide Environmental Impact Statement for Continued Operation of Lawrence Livermore National Laboratory and Supplemental Stockpile Stewardship and Management Programmatic Environmental Impact Statement", U.S. Department of Energy, National Nuclear Security Administration, DOE/EIS-0348, DOE/EIS-0236-S3 (March 2005).

DOE 2006: "Need to Consider Intentional Destructive Acts in NEPA Documents", Memorandum to DOE NEPA Community form the Office of NEPA Policy and Compliance (December 1, 2006).

DOT 1998: U.S. Department of Transportation, "Hazardous Materials Shipments," Office of Hazardous Materials Safety; Research and Special Programs Administration, US DOT (October 1998).

DOT 2001a: U.S. Department of Transportation, "A Comparison of Risk; Accidental Deaths – United States – 1994-1998," US DOT Research and Special Programs Administration, http://hazmat.dot.gov/riskcompare.htm.

DOT 2001b: U.S. Department of Transportation, Hazardous Materials Safety Data from the Hazardous Materials Information System (HMIS), from on-line website http://hazmat.dot.gov/spills.htm.

Fleming et al., 1995: D. O. Fleming, J. H. Richardson, J. I. Tulis, and D. Vesley, "Laboratory Safety; Principles and Practices," 2nd Edition, American Society for Microbiology, Washington, DC (1995).

Fleming and Hunt 2000: Diane O. Fleming and Debra L. Hunt, "Biological Safety: Principles and Practices, 3rd Edition," American Society for Microbiology Press, Washington, DC (October 22, 2000).

GAO 2007: General Accounting Office, "High-Containment Biosafety Laboratories, Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States," Statement of Keith Rhodes, Chief Technologist, Center for Technology and Engineering, Applied Research and Methods, General Accounting Office, Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, Washington, D.C. GAO-08-108T (October 4, 2007).

Houston Chronicle 2007: "CDC finds breaches at A&M disease lab / Research will remain on hold as missing vials, security missteps are addressed," Houston Chronicle Publishing Company Division, Hearst Newspapers Partnership, L.P., Houston, Texas (September 5, 2007) [available on-line at http://www.chron.com/CDA/archives/archive.mpl?id=2007_4418410]

Gray 1978: T. R. G. Gray, "Microbiological aspects of the soil, plant, aquatic, air, and animal environments," Pesticide Microbiology, I. R. Hill and S. J. L. Wright (eds.), Academic Press, New York, NY (1978).

HRSA 2000: Health Resources and Services Administration, "Community Health Status Report: Alameda County, California, July 2000," U.S. Department of Health and Human Services, Health Resources and Services Administration (July 2000). [available on-line at http://www.communityhealth.hrsa.gov]

Hugh-Jones 1998: Martin Hugh-Jones, "1996-1997 Global Anthrax Report," Proceedings of the Third International Conference on Anthrax, Plymouth, England, (September 7-10, 1998). [available on-line at http://www.vetmed.lsu.edu/whocc/globrept.htm}

IATA 2001: International Air Transport Association (IATA), "Dangerous Goods Regulations," and "Infectious Substances Shipping Guidelines," Montréal, Québec, Canada (2001).

JH 1999: Johns Hopkins University, "CDC Ranks Bioagents in Terms of Public Health Threat," Johns Hopkins Center for Civilian Biodefense Studies, Biodefense Quarterly, Vol. 1, No. 2 (September 1999).

Kennedy et. al 1990: Robert P. Kennedy, Stephen A. Short, James R. McDonald, Martin W. McCann, Jr., Robert C. Murry, and James R. Hill, "Design and Evaluation Guidelines for Department of Energy Facilities Subjected to Natural Phenomena Hazards," University of California, Livermore, CA, UCRL-15910 (June 1990).

LLNL 1991: Lawrence Livermore National Laboratory, "AB2588 Air Toxics Risk Screening Document for Lawrence Livermore National Laboratory, Plant No. 255, Lawrence Livermore National Laboratory, Livermore, CA (February 1991).

LLNL 1993: Lawrence Livermore National Laboratory, "Calendar Year 1993 Calculated Emissions Inventory, BAAQMD Plant No. 255, Lawrence Livermore National Laboratory (1993)

LLNL 1994: Lawrence Livermore National Laboratory, "Waste Minimization and Pollution Prevention Awareness Plan," University of California, Livermore, CA, UCRL-21215-94 (April 1994).

LLNL 2000a: Lawrence Livermore National Laboratory, "Building 360 Complex; Biology and Biotechnology Research Program (BBRP)," University of California, Livermore, CA, FSP 360, Triennial Review (May 2000).

LLNL 2001a: Lawrence Livermore National Laboratory, "Building 360 Complex, Biohazardous Operations," University of California, Livermore, CA, FSP-360 Addendum 1, Triennial Review (April 2001).

LLNL 2001b: Lawrence Livermore National Laboratory, "Environmental Report 2000," University of California, Livermore, CA, UCRL-50027-00 (September 1, 2001).

LLNL 2001c: Lawrence Livermore National Laboratory, "ES&H Manual," University of California, Livermore, CA, UCRL-MA-133867 (April 1, 2001).

LLNL 2002: LLNL, *Lawrence Livermore National Laboratory Site Seismic Safety Program: Summary of Findings*, UCRL-53674, Rev. 2, Lawrence Livermore National Laboratory, Livermore, CA, April 2002.

LLNL 2005: Lawrence Livermore National Laboratory, "Biological Risk and Threat Assessment," University of California Livermore, CA (July 14, 2005).

LLNL 2006: Lawrence Livermore National Laboratory, "LLNL Select Agents and Toxins Security Plan," Revision 6, University of California Livermore, CA, SSO-POL-010, UCRL-MI-220409 (March 9, 2006).

Magreb 1975: E. B. Magreb, "Environmental Noise Control," Wiley-Interscience Publication, John Wiley & Sons, New York, NY (1975).

NFPA 1997: National Fire Protection Association, " Standard for the Installation of Lighting Protection Systems," NFPA 780, 1997 Edition.

NFPA 1998: National Fire Protection Association, "NFPA 70, National Electrical Code," NFPA 70, 1999 Edition (August 6, 1998).

NFPA 2000: National Fire Protection Association, "Life Safety® Code," NFPA 101®, 2000 Edition.

NIH 2001: National Institutes of Health, "Guidelines for Research Involving Recombinant DNA Molecules," published as 59 FR 34496 and amended through 66 FR 1146, available on-line through NIH website: http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html.

Noskin and Peterson 2001: Gary A. Noskin and Lance R. Peterson, "Engineering Infection Control through Facility Design," Centers for Disease Control and Prevention, Emerging Infectious Diseases, Vol. 7, No. 2, pages 354-357 (April 2001).

NSC 1996: National Safety Council, "Fourth Edition: Fundamentals of Industrial Hygiene," Barbara A. Plog Editor, Itasca, Illinois (1996).

Orloff 1986: S. Orloff, "Wildlife Studies of Site 300 Emphasizing Rare and Endangered Species, Lawrence Livermore National Laboratory, San Joaquin County, California, prepared by BioSystems Analysis Inc., for Lawrence Livermore National Laboratory, CA (1986).

PC 2001a: Personal communication concerning biosafety laboratory construction and operation between Dr. Richard Knudsen, Chief Scientist, Biosafety Branch, Special Pathogens Branch, and Robert Hull, Los Alamos Technical Associates, Inc., June 12, 2001.

PC 2001b: Personal communication concerning biosafety laboratory construction and operation between Dr. Joe McDade, Deputy Director CDC National Center for Infectious Diseases (NCID), Special Pathogens Branch, and Robert Hull, Los Alamos Technical Associates, Inc., June 14, 2001.

PC 2002: Personal communication concerning biosafety laboratory construction and operation between Alan B. Casamajor, PE, Assurance and Facility Manager, Biology and Biotechnology Research Program, LLNL, and Robert Hull, Los Alamos Technical Associates, Inc., May, 2002.

Pike et al. 1965: R. M. Pike, S. E. Sulkin, and M. L. Schulze, "Continuing importance of laboratory-acquired infections," American Journal of Public Health, Vol. 55, pages 190-199 (1965).

Pike 1976: R. M. Pike, "Laboratory-associated infections: Summary and analysis of 3,921 cases," Health Laboratory Science Vol. 13 pages 105-114 (1976).

Pike 1979: R. M. Pike, "Laboratory-associated infections: incidence, fatalities, causes and prevention," Annual Reviews of Microbiology, Vol. 33, pages 41-66 (1979).

Sewell 1995: David L. Sewell, "Laboratory-Associated Infections and Biosafety," Clinical Microbiology Reviews, Vol. 8, No. 3, pages 389-405 (July 1995).

SNL/LLNL 2006: Sandia National Laboratories and Lawrence Livermore National Laboratory, "Catastrophic Bioterrorism Scenarios: Response Architectures and Technology Implications" (March 2006).

Stocker, 1955: Stocker MGP, Morrison BP. "The spread of Q fever from animals to man: the natural history of rickettsial disease," Bull. WHO 1955.

Sulkin and Pike 1949: S. E. Sulkin and R. M. Pike, "Viral infections contracted in the laboratory," New England Journal of Medicine, Vol. 241, No. 5, pages 205-213.

Sulkin and Pike 1951: S. E. Sulkin and R. M. Pike, "Survey of laboratory-acquired infections." American Journal of Public Health, Vol. 41, No. 7, pages 769-781 (1951).

USAMRMC 2006: "Final Environmental Impact Statement, Construction and Operation of the New U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) Facilities

and Decommissioning and Demolition and/or Re-use of Existing UASMRIID Facilities at Fort Detrick, Maryland," U.S. Army Medical Research and Material Command, Fort Detrick, MD (December 2006).

USFWS 1991: U.S. Fish and Wildlife Service, "Letter of Communication, Subject: Species Lists for the Proposed Future Growth of Lawrence Livermore National Laboratory (LLNL) and Sandia National Laboratories, Livermore (SNLL) Areas, and the Site 300 Area, Alameda and San Joaquin Counties, California", U.S. Department of the Interior, Fish and Wildlife Service, Sacramento Field Office, Sacramento, CA (March 5, 1991).

USGS 2003: U.S. Geologic Survey (USGS), *Earthquake Probabilities in the San Francisco Bay Region: 2002-2031,* USGS OFR 03-214, (2003), online at http://pubs.usgs.gov/of/2003/of03-214/.

Welsh et al 1951**:** H. H. Welsh, E. H. Lennette, F. R. Abinati, and J. F. Winn, "Q fever in California IV: Occurrence of *Coxiella burnetti* in the placenta of naturally infected sheep," *Public Health Reports*, 66(45):1473-7, 1951

WHO 1997: World Health Organization, "Guidelines for Safe Transport of Infectious Substances and Diagnostic Specimens," Division of Emerging and Other Communicable Diseases Surveillance and Control, Geneva, Switzerland (1997).

WHO 1998: World Health Organization, "Guidelines for the Surveillance and Control of Anthrax in Humans and Animals; Third Edition," PCB Turnbull, Department of Communicable Diseases Surveillance and Response, Geneva, Switzerland (1998).

WHO 1999: World Health Organization, "International Statistical Classification of Diseases and Related Health Problems (ICD-10) in Occupational Health," Sustainable Development and Healthy Environments, Protection of the Environment; Occupational and Environmental Health Series, WHO/SDE/OEH/99.11, Geneva, Switzerland (1999).

WHO 2001: World Health Organization, "World Anthrax Data Site," "News of Anthrax Cases and Outbreaks form Around the World, May 2000 – February 2001," available on-line at: http://www.vetmed.lsu.edu/whocc/news.htm.

Wilson 1995: Mary E. Wilson, "Travel and the Emergence of Infectious Diseases," Centers for Disease Control and Prevention, Emerging Infectious Diseases, Vol. 1, No. 2, pages 40-46 (April-June 1995).

EXHIBIT 2

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

TRI-VALLEY CARES, et al.,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF ENERGY, et al.,

Defendants.
_____/

No. C 03-3926 SBA

ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND DENYING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT OR IN THE ALTERNATIVE PARTIAL SUMMARY JUDGMENT

This matter comes before the Court on the motion for summary judgment, filed by defendants United States Department of Energy ("DOE"), National Nuclear Security Administration ("NNSA"), Lawrence Livermore National Laboratory ("LLNL"), and Los Altos National Laboratory ("LANL") (collectively, "Defendants"), and the motion of Tri Valley Cares, et al., ("Plaintiffs") for summary judgment or in the alternative for partial summary judgment. Having read and considered the arguments presented by the parties in their moving papers, the Court finds this matter appropriate for disposition without a hearing. The Court hereby GRANTS Defendants' motion for summary judgment and DENIES Plaintiff's motion for summary judgment or in the alternative partial summary judgment.

BACKGROUND

A. Factual Background

The National Nuclear Security Administration (NNSA) of the Department of Energy (DOE) is

responsible for national programs to address biological, chemical, and nuclear threats to the country. Lawrence Livermore National Laboratory (LLNL) hosts NNSA research in support of this goal. This research requires that the laboratory contain infectious agents that pose risks to human health. *See* LLNL AR1 at ii-iii.[1]

The Center for Disease Control (CDC) and the National Institutes of Health (NIH) maintain guidelines — "accepted as the international 'gold standard' for safely conducting microbiological research," according to the CDC—that define four distinct safety levels for facilities that conduct biological research. *See id.* at A-2. These levels, known as Biosafety Levels (BSL) 1 through 4, require increasingly rigorous safeguards to protect laboratory personnel and the environment. *Id.* The CDC and the NIH assign BSLs to individual biological agents. *Id.* at 1 n.2.

DOE does not currently operate any facilities beyond BSL-2, but the agency has determined that "key elements" of its research agenda require the containment standards of a BSL-3 facility. *Id.* at ii. Though there are more than 250 BSL-3 facilities within the United States, including facilities at the San Francisco and Davis campuses of the University of California, the agency has determined that these facilities have already been committed to other projects or are otherwise unsuitable for its needs. *Id.* at ii, C-9. DOE therefore proposes the assembly of a one-story, 1500 square-foot BSL-3 facility at LLNL with an operational design life of 30 years. *Id.* at ii. DOE also discusses several design alternatives, including one in which no new BSL-3 facility is constructed; this "No Action Alternative" would "not meet the NNSA's identified purpose and need for action." *Id.* at iii.

Pursuant to the National Environmental Policy Act of 1969 (NEPA), the DOE prepared an Environmental Assessment (EA), the purpose of which was to determine whether to prepare a full Environmental Impact Statement (EIS) or to issue a Finding of No Significant Impact (FONSI). The DOE first issued a draft EA on July 24, 2002; this was followed by a public comment period that ended on September 7, 2002. In December 2002, the DOE issued a final EA. Based on this EA, the DOE then chose to issue a FONSI and to authorize construction of a BSL-3 facility at LLNL.

---

[1]Citations to LLNL AR refer to the portion of the case's administrative record concerning the Lawrence Livermore National Laboratory, which begins with the Environmental Assessment (EA) performed by the DOE.

Plaintiffs are: several individuals who live near LLNL; an organization which represents their interests and of which they are members; and several other parties. Plaintiffs challenge the DOE's FONSI (and its authorization to construct the BSL-3 facility) under NEPA, 42 U.S.C. §§ 4321-4370d, arguing that the EA is insufficient and that it ignores numerous dangers and threats. Plaintiffs also challenge the DOE's alleged failures to: (1) file a programmatic EIS (PEIS) pursuant to the Council of Environmental Quality's NEPA regulations, 40 C.F.R. § 1508.25, for DOE's nationwide Chemical and Biological National Security Program (CBNP); (2) file a site-wide EIS for LLNL; and (3) respond to requests issued by Plaintiffs under the Freedom of Information Act (FOIA), 5. U.S.C. § 552.

B. Procedural Background

In a May 2004 Order, this Court considered Defendants' motion to strike certain declarations Plaintiffs submitted in support or their motion for summary judgment and their opposition to Defendants' motion for summary judgment. The Court granted the motion in part, and struck most of the declarations as being extra-record materials. Generally, in reviewing an administrative decision, this Court may only consider information that was available at the time the Agency made its decision. Airport Cmty. Coalition v. Graves, 280 F. Supp. 2d 1207, 1213 (W.D.Wash.2003) (noting that consideration of "new information represents 'Monday morning quarter backing.' If the court were to consider this new information in an arbitrary and capricious analysis, the court would effectively transform that analysis into de novo review, a level of review for which the court is not authorized.")

The Court, however, did allow certain declarations (or portions of them), based on the Ninth Circuit's rule that there are four exceptions in which a court may consider extra-record materials in APA cases. Those four exceptions are: (1) to determine whether the agency has considered all relevant factors and has explained its decision; (2) when the agency has relied upon documents or materials not included in the record; (3) when necessary to explain technical terms or complex matters; and (4) when Plaintiffs make a showing of agency bad faith. Southwest Center for Biological Diveristy v. United States Forest Service, 100 F.3d 1443, 1450 (9th Cir. 1996).

1. Declarations Struck by the Court

The Court struck the following declarations in whole:

(1) the Declaration of Colin King;

(2) the Declaration of Susan Wright;

(3) the Declaration of Mark Wheelis;

(4) the Declaration of Scott Ritter;

(5) the Declaration of Marylia Kelley;

(6) the Declaration of Peter Strauss;

(7) the Declaration of Dolores Gallego;

(8) the Declaration of Peter Stockton.

2. Declarations or Portions of Declarations Admitted by the Court

The Court admitted the following declarations to assist it in determining whether DOE considered all the relevant factors in issuing the EA:

(1) only Paragraphs 1 and 3 of the Declaration of James Coughlan, to establish Plaintiffs' standing;

(2) those portions of the Declaration of Matthew Zipoli referencing a report on LLNL security entitled Inspection of Lawrence Livermore National Laboratory Protective Force and Special Response Team (the "Report"), and those portions of the declaration referencing his personal observations as a Security Officer at LLNL between January 1999 and September 2001;[2]

(3) the Declaration of Terrell Watt regarding safety issues;

(4) the Declaration of Marion Fulk regarding HEPA filters;

(5) the Declaration of Robert Curry, Paragraphs 6 and 7, in which Professor Curry provides facts regarding the proximity of fault lines;

(6) the Declaration of Edward Hammond, but only those paragraphs that provide a list of BSL-3 labs that are already operating or are proposed by other entities;

(7) the Declaration of Matthew McKinzie regarding accidental release analysis based on a drastic event such as an earthquake.

3. Rebuttal

[2]The Court struck from Mr. Zipoli's Declaration statements that constituted legal conclusions and newspaper articles from Spring 2003 because the articles could not have been considered by DOE during the decision making process; they post-dated it.

In the May 2004 Order, the Court granted Defendants leave to file rebuttal declarations because they had not had an opportunity to respond to the extra record materials. Defendants timely filed the declarations. Because "[a] satisfactory explanation of agency action is essential for adequate judicial review....." Asarco, Inc. v. U.S. Environmental Protection Agency, 616 F.2d 1153, 1160 (9th Cir. 1980), Defendants' response was essential to this Court's review of the underlying motions.

PROCEDURAL ISSUES

The Court has set forth in detail its May 2004 Order for two reasons. First, in reviewing Plaintiffs' motion for summary judgment and Plaintiffs' opposition to Defendants' motion for summary judgment, the Court observes that some of Plaintiffs' arguments rely on the stricken declarations. Having stricken those declarations for the reasons set forth in the May 2004 Order, the Court will not consider them in determining Plaintiffs' motion, nor Defendants'. They are not part of the record.

Second, on June 30, 2004, Plaintiffs submitted a motion for leave to file reply declarations to Defendants' rebuttal declarations. Plaintiffs were already given one bite at the proverbial apple to submit the extra-record declarations and the Court granted Defendants an opportunity to reply because they had not had an opportunity to respond. Plaintiffs' purported "reply" declarations are nothing more than a perpetual battle of the experts, a battle in which this Court will not participate. *See Marsh v. Oregon Natural Res. Council*, 490 U.S. 360, 378 (1989). As such, they are not appropriate for the Court's consideration. The motion for leave to file reply declarations is DENIED.

ADMINISTRATIVE REVIEW UNDER THE APA

A. Standard of Review

Because NEPA does not create a private right of action, Plaintiffs' challenges to DOE action is governed by the Administrative Procedure Act (APA), 5 U.S.C. § 701 *et seq*. *See Lujan v. National Wildlife Federation*, 497 U.S. 871, 882 (1989). The APA provides that a "person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of the relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.

The APA limits the scope of judicial review of agency actions. In general, a court may not set aside an agency action unless that action was "arbitrary and capricious, an abuse of discretion, or otherwise not in

accordance with the law." 5 U.S.C. § 706(2)(A). In reviewing agency action, the Court must be "highly deferential" to the agency; the Court's review is "narrow," and it "may not set aside agency action as arbitrary or capricious unless there is no rational basis for the action." *Friends of the Earth v. Hintz*, 800 F.2d 822, 831 (9th Cir. 1980).

In a NEPA challenge, a court cannot "substitute [its] judgment for that of the agency concerning the wisdom or prudence of a proposed action." *Laguna Greenbelt, Inc. v. United States Dep't of Transp.*, 42 F.3d 517, 523 (1994). In this case, the Court's only role is to review the agency's EA to ensure that the DOE gave the "required 'hard look'" at the environmental consequences of its decisions. *See Kettle Range Conservation Group v. United States Forest Serv.*, 147 F.3d 1155, 1157 (9th Cir. 1998). A court's "scope of review does not enable [it] to decide whether [it] would have given the same hard look and reached the same conclusion." *Id.*

"[A]n agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive." *Marsh v.* 490 U.S. at 378. *See also Friends of Endangered Species, Inc. v. Jantzen*, 760 F.2d 976, 986 (9th Cir. 1985) ("[N]or does NEPA require us to resolve disagreements among various scientists as to methodology"); *Life of Land v. Brinegar*, 485 F.2d 460, 472 ("disagreement among experts will not serve to invalidate an EIS"); *Webb v. Gorsuch*, 699 F.2d 157, 160 (4th Cir. 1983) ("When there is conflicting expert opinion, it is for the administrative agency and not the courts to resolve the conflict.").

B. Plaintiffs' challenge of the EA for LLNL

Plaintiffs challenge, on several grounds, the DOE's EA for the proposed BSL-3 facility at LLNL and the DOE's decision to issue a FONSI for this facility.

First, Plaintiffs argue that the EA inadequately addresses *threats* arising from (a) the DOE's historical safety record; (b) transportation of biological agents to and from the proposed facility; (c) damage to the community from "abnormal events," such as earthquakes and terrorist attacks, that could trigger a release of pathogens; and (d) deficiencies in the lab's HEPA-filtration systems.

Second, Plaintiffs argue that the EA inadequately addresses the *precedential effects* of the proposed facility.

Third, Plaintiffs argue that the EA inadequately addresses the *controversy* surrounding the

proposed facility.

Fourth, Plaintiffs argue that the EA inadequately addresses the *cumulative effects* of the proposed facility.

1. Threats posed by the proposed BSL-3 facility

a. DOE's safety record generally, and DOE's ability to ensure the safety of routine operations at LLNL

Plaintiffs argue that DOE in general and LLNL in particular have "poor safety, security, and compliance records, rendering a presumption of full compliance unreasonable." Pls.' SJ Br. at 5. To support this proposition, Plaintiffs cite several letters sent to DOE during the EA's public comment period. *See id.* The EA, however, does consider the historical record of CDC-registered laboratories since 1974 and the safety record of LLNL over the past 20 years. The EA cites several facts about this historical record:

- "Based on information provided by the LLNL [Biology and Biotechnology Research Program] Assurance and Facility Manager, LLNL has operated BSL-1- and BSL-2-equivalent laboratories for at least the last 20 years without any infections associated with their operation." LLNL AR1 at 41.
- "[T]he LLNL BBRP Assurance and Facility Manager reviewed available Occurrence Reporting and Processing System (ORPS) Reports (from the past 10 years)." *Id.*
- "[T]here were no unintentional releases to the environment or to the public associated with the LLNL biological research laboratories." *Id.* That is, "LLNL has operated BSL-1- and BSL-2-equivalent laboratories for the last 20 years without any . . . unintentional releases to the environment or to the public." *Id.* at C-3.

Although the EA acknowledges anecdotal reports of infrequent safety and health issues associated with BSL-3 laboratories in general, it determines that BSL-3 and similar facilities do not normally or regularly cause "disease-related health effects [for] workers, their families, or the general public." *See* LLNL AR1 at 41. This determination, which cites to specific facts, has a reasonable basis.

The EA also considers the experience of the Biological Defense Research Program (BDRP) facilities operated by the U.S. Department of the Army. *See* LLNL AR1 at 40-41. One letter cited by

Plaintiffs questions the applicability of the Army's historical experience to that of the DOE: "There is no explanation for why we should believe that the safety culture at the Army laboratories is the same as that at the Department of Energy." LLNL AR1 at C-62. However, it is for the DOE and not this Court to decide the appropriate inferences to be drawn from a reasonable analogy. *Laguna Greenbelt*, 42 F.3d at 523. The EA's consideration of the historical safety records of similar, non-DOE facilities is not arbitrary or capricious.

Moreover, the EA responds directly to the comments submitted during the comment period and notes that while accidents are unavoidable, "LLNL has had an infrequent history of incidents and none has resulted in a significant impact to the public or the environment." LLNL AR at C-3. Plaintiffs have not successfully undermined the reasonableness of this assessment.

Even if the DOE has encountered historical problems at other facilities, the EA documents DOE's attempts to address them. For instance, the administrative record includes the EA for a proposed BSL-3 facility at the Los Alamos National Laboratory (LANL), which includes a report from the DOE Inspector General documenting "responsive" "corrective actions" taken by DOE to address earlier problems. LLNL AR37 at B-35. *See generally id.* at B-1 through B-40.

Plaintiffs' arguments may also be taken to suggest that DOE will, in bad faith, choose not to follow the safety and security procedures outlined in the EA. However, administrative agencies are entitled to a presumption that "they will act properly and according to law." *FCC v. Schreiber*, 381 U.S. 279, 296 (1965). Moreover, the EA notes that the Center for Disease Control (CDC) is authorized to inspect all BSL-3 facilities periodically, and DOE's operating contract with the University of California requires that LLNL implement the CDC/NIH guidelines. *See id.* at C-4, C-9. Thus, not only must the Court presume that the DOE will act in good faith, but the record shows that third parties can intervene to ensure that DOE complies.

b. Transportation of BSL-3 agents

Plaintiffs argue that the EA "fails entirely to analyze" the risks that arise from the need to transport hazardous biological materials to the proposed BSL-3 facility. Pl. SJ Br. at 5. However, the EA notes the following considerations:

- Deliveries of biological materials and infectious agents can be shipped to the BSL-3 facility

only by authorized entities such as commercial package-delivery services and the U.S. Postal Service. LLNL AR1 at 22.

- All incoming packages that contain infectious agents will be required to meet Department of Transportation (DOT) guidelines, 42 C.F.R. 72. Samples will be "double- or triple-contained." *Id.*
- Interstate shipment and import of biomedical materials is subject to the requirements of the U.S. Public Health Service Foreign Quarantine. *Id.* *See also* 42 C.F.R. 71.
- The U.S. Department of Agriculture regulates the interstate shipment and import of "animal and plant pathogens." *Id.* *See also* 7 C.F.R. 330, 9 C.F.R. 92.
- Individual shipments of samples will typically be small; "the maximum probable sample size would be 15 milliliters," and the typical one will be smaller. *Id.*

The EA thus outlines detailed regulations and procedures that govern the transportation of agents to be shipped to the proposed facility.

Moreover, the EA notes the vast quantities of hazardous materials currently shipped within the United States and the low risk to the public from such shipments. *Id.* at 54. In addition, there are over 250 BSL-3 facilities already operating in the United States. Based on this data, the EA concludes that "the addition of milliliter-quantity samples shipped to and from the BSL-3 facility [at LLNL] . . . would not be expected to change the overall incidence of risk of transportation accident."

Similarly, the EA responds to the letters received during the public-comment period as follows:

> Federal and commercial carriers have been transporting appropriately packaged biological samples for many years . . . . Hospitals, laboratories, schools, universities, and teaching facilities engage in the transport of biological samples in large numbers every day. Any increase in the risk of accident or terrorist attack because of shipments associated with the proposed BSL-3 facility at LLNL would be negligible.

LLNL AR1 at C-14.

Plaintiffs also contend that the EA should "describe and evaluate"—not merely cite—protective regulations concerning the transportation of biological agents. That is, Plaintiffs appear to attempt to distinguish the "actual environmental threat" from the threat permitted by regulations. Plaintiffs cite *Sierra Club v. Marsh*, 769 F.2d 868 (1st Cir. 1985) for this proposition. This case appears to be inapposite, however. The First Circuit in *Marsh* rejected a defendant's reliance on "local, state, and Federal

regulations" only because the relevant regulations were insufficient to prevent the type of damage NEPA was intended to prevent; it did not reject the reliance on regulations simply because they were regulations.

Given that the EA describes comprehensive regulations and discusses the additional impact of the proposed facility on the nation's transportation infrastructure, the Court finds that the DOE has taken a "hard look" at the transportation risks associated with the proposed BSL-3 facility. *Kettle Range Conservation Group* 147 F.3d at 1157.

c. Damage to the community from "abnormal events," such as earthquakes and terrorist attacks, that could trigger a release of pathogens

Plaintiffs argue that the EA's analysis of the threat to the environment and to the health of the surrounding communities from an accidental release of hazardous material from the proposed BSL-3 facility was inadequate in four respects. First, Plaintiffs dispute the EA's analysis of the consequences of accidental release in general. Second, Plaintiffs dispute the EA's analysis of the damage to the facility from earthquakes. Third, Plaintiffs dispute the EA's analysis of the risks of terrorist attacks, sabotage, and other matters of security. Fourth, Plaintiffs raise new accident scenarios that they believe the EA failed to consider.

I. The consequences of accidental release

The EA includes a model of an "accident scenario" premised on several assumptions, such as the time of day of the accidental release, the wind speed during the accidental release, and so forth. *See* LLNL AR1 at B-9 to B-11. Plaintiff argues that this model is inadequate because: (a) it fails to consider structural breaches; (b) it is based on a non-representative biological agent; and (c) it fails to account for nearby freeways.

1. Failure to analyze structural breaches

First, Plaintiffs note that the modeled scenario assumes that any accidental release of hazardous materials would first pass through a HEPA filter. *See* Pls.' Consol Opp at 5, LLNL AR1 at B-11. Plaintiffs argue that such an assumption fails to consider the possibility that the proposed facility's walls could be breached; a breach might allow hazardous materials to escape the facility without passing through any filter. However, the EA explains the context of the hypothetical "accident scenario" as follows:

[A] release to the environment from a catastrophic event would require several

> simultaneous conditions to coexist: a worker is transferring a quantity of infectious material when the catastrophic event occurs; the containers aren't properly sealed; the entire set of containers is dropped; the containers break open; and the catastrophic event simultaneously causes a structural breach in the BSL-3 containment walls.

LLNL AR1 at 50. The EA also notes that "according to the U.S. Army . . . the likelihood of such catastrophic occurrences is too small to be considered as reasonably foreseeable. No such event has occurred in the more than 50 years in which the military has been conducting biological defense research activities." *Id.*

The Court finds that the DOE indeed took the requisite "hard look" at the possibility of structural breach. *See Kettle Range Conservation*, 147 F.3d at 1157. There is nothing arbitrary or capricious in the finding that accidental releases of biological materials will be filtered. In coming to this conclusion, the EA noted the circumstances under which filtering would fail, and also noted that no such event had occurred in over half a century .

2. Choice of biological agent

Plaintiffs also argue that the model's use of *Coxiella burnetti* (Q-fever) as the biological agent released in the "accident scenario" is inappropriate because "direct transmission of Q-fever from person to person is rare." Pls.' Consol.Op at 5. However, the EA claims to have chosen Q-fever because it is "highly durable, infectious, and transmissible, and has excellent environmental survivability." LLNL AR1 at 51. Moreover, the EA claims that other microorganisms were considered but rejected either because: (a) they pose less of a risk to human health; or (b) because they are less resilient in the environment. *Id.* Finally, the EA notes that not only the DOE, but the CDC, has decided that Q-fever "probably represents the greatest risk of laboratory infection." LLNL AR1 at B-11. The Court is satisfied with this analysis; the disagreement about what organism to use is a disagreement among experts, and, as discussed *supra*, "an agency must have discretion to rely on the reasonable opinions of its own qualified experts." *Marsh v. Oregon Natural Res. Council*, 490 U.S. at 378.

Plaintiffs have not given this Court any reason to find that the choice of Q-fever was arbitrary, capricious, or otherwise disingenuous.

3. Proximity of Interstate Highway 580

The Watt declaration notes the increasing human population of the San Francisco Bay Area. It also

claims that Interstate Highway 580 is one of California's busiest freeways, that its proximity to the proposed BSL-3 facility at LLNL could expose tens of thousands of travelers to potentially lethal dosages of hazardous materials, and that the EA ignores some related consequences of an accidental release of hazardous materials. *See* Watt Declaration ¶¶ 5-8. These conclusions are based on an analysis model known as Hazard Prediction and Assessment Capability (HPAC), which is used to predict the health risk that would result from damage to a facility that stores or produces biological weapons.

In an administrative review, this Court cannot choose among the detailed parameters provided by competing experts. *Marsh v. Oregon Natural Res. Council*, 490 U.S. at 378 ("[A]n agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive."); *Webb v. Gorsuch*, 699 F.2d. at 160 ("When there is conflicting expert opinion, it is for the administrative agency and not the courts to resolve the conflict."). The only question for this Court is whether the EA should have included an assessment of potential damage using the HPAC modeling technique.

Defendants submitted the declarations by Ron Durling and Robert Hull to explain why the HPAC model is not appropriate. The HPAC model assumes that pathogens are weaponized. Mr. Durling claims that the type of anthrax to be used in the proposed BSL-3 facility "simply will not behave like weaponized material, and thus is not accurately modeled by HPAC." Durling Declaration ¶ 4. Mr. Hull also notes that the EA considered many accident-initiating threats and that the DOE performed an "extensive literature search" and discussed historical data about accidental releases with the CDC, NIH, and the Army. Hull Declaration ¶ 10 (citing LLNL AR1 at 49-50, B-7 to B-9, C-9 to C-10).

Given that it is within DOE's discretion to rely on the opinions of its experts, and that the EA reflects that DOE considered the sound reasoning of several experts regarding accidental releases, the Court finds that DOE was not arbitrary or capricious in choosing not to use the HPAC model.

4. Other Accident Scenarios

Plaintiffs also suggest that the EA's "accident scenario" overlooks the possibility that a laboratory worker will leave the facility without realizing that he or she had been exposed. However, the EA and the data it cites consider such possibilities, at least indirectly. For instance, the EA notes that laboratory workers will be vaccinated against Q-fever. *See* LLNL AR1 at B-11.

Moreover, Plaintiffs cannot impugn the EA's analysis by introducing new speculative disaster scenarios. The EA must be evaluated based on information and analysis within the record. *See, e.g.*, *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985) ("The focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.") Plaintiffs cite no adequate basis for their argument that the EA overlooked the possibility that an infected worker would spread infections to others; instead, they cite only LLNL AR17 at 3-5, a CDC report that discusses mass infection of the public by terrorists who release biological agents covertly. The analogy between a release of pathogens by terrorists and the danger posed by an unwitting laboratory worker is too tenuous to substantiate Plaintiffs' argument.

ii. Damage to the facility from earthquakes

The previous section considered the EA's analysis of the general *consequences* of an accidental release of hazardous materials. A separate question is whether the EA properly considers particular threats that increase the *likelihood* of such releases. This section considers the particular risk from seismic activity. As discussed *supra*, even if the EA does not properly account for the likelihood of accidents, it properly accounts for the consequences of such accidents and finds these consequences to be minimal.

Plaintiffs rely largely on the Curry declaration, most of which has been stricken pursuant to the Court's May Order. After eliminating arguments that depend only on the stricken portion of the Curry declaration, Plaintiff's remaining arguments are that: (a) the EA improperly estimates the ground motion that can be "reasonably expected"; and (b) that the EA improperly rests on the incorrect assessment that there are no "active faults . . . in proximity to the location of the proposed facility." *See* LLNL AR1 at 36.

The first of these arguments amounts merely to a disagreement among experts; and the Court must defer to DOE's choice of experts. *Marsh v. Oregon Natural Res. Council*, 490 U.S. at 378. Indeed, the Court previously found that Mr. Curry's challenge to the EA's estimates of ground motion were "simply contrary opinions" and were thus inadmissible in a review under the APA.

The second of these arguments depends on factual assertions in the Curry declaration. The Defendants respond to these factual assertions with a declaration of Dr. Madhu Kamath, the principal structural engineer for LLNL's Plant Engineering Department. The Kamath declaration disputes Dr. Curry's factual assertions; defends the truth of the EA's statement that there are no "active faults . . . in

proximity to the location of the proposed facility" by noting that the "fault zones" delineated by the California State Geologist and shown by the EA's map, LLNL AR1 at 37, do not extend into the LLNL site; and notes that LLNL AR1 at C-10 describes the DOE standard governing the construction of the proposed facility. Plaintiffs have not demonstrated that this DOE standard, or the process used by the DOE generally in evaluating earthquakes, is arbitrary or capricious.

iii. Terrorist attacks, sabotage, and other matters of security

1. The threat of terrorism

Plaintiffs allege that the EA fails to analyze the proposed facility's vulnerability to terrorist attacks, particularly those that involve trucks (as in Oklahoma City) or airplanes (as on September 11, 2001). The EA admits that it does not describe the potential results of terrorist attacks. *See* LLNL AR1 at C-12.

Defendants note that the "accident scenario," discussed in the foregoing analysis, is applicable to *all* releases, irrespective of their cause. Threats from truck- or airplane-based terrorism do not, according to the EA, have different dispersal patterns from those associated with fires or earthquakes. *See* LLNL AR1 at C-13. Plaintiffs have given the Court no reason to question this statement—and they have certainly not demonstrated that relying on it would be arbitrary and capricious. Moreover, Defendants note that the EA explicitly considers "explosions and airplane crashes" in general and finds that such events may actually "reduce the consequences of microbiological material releases" because heat, fire, sunlight, and wind can render hazardous biological materials innocuous. *See* LLNL AR1 at 49.

2. LLNL's security officers

Plaintiffs argue that LLNL's security is "grossly inadequate." Pl.'s Motion at 3. To support this contention, they introduce the declaration of Matthew Zipoli, a security officer who has worked at LLNL.

The Zipoli declaration cites several instances and practices that suggest poor standards of security at LLNL. For instance, Mr. Zipoli claims that security-officer trainees were encouraged by instructors to cheat during DOE performance examinations, that officers receive inadequate training, and that security procedures are sometimes rushed or generally inadequate. *See* Zipoli Declaration ¶¶ 5-12. Mr. Zipoli also cites a DOE Inspector General report from December, 2001; this report describes inadequate security practices and staffing deficiencies. Zipoli Declaration ¶ 13.

Defendants respond with a declaration of Michel Dahlstrom, LLNL's Principal Security

Administrator. This declaration (a) questions the basis for some of Mr. Zipoli's observations; (b) directly contradicts others; and (c) claims that many other observations do not pertain directly to the security of the proposed BSL-3 facility. For instance, the Dahlstrom declaration makes the following claims:

(a) Mr. Zipoli "would not have been in a position" to determine whether the reassignment of officers—a fact Mr. Zipoli notes in his declaration—would compromise the overall security of LLNL. Dahlstrom Declaration ¶ 5(g).[3]

(b) Mr. Zipoli's claims concerning cheating have not been "validated by any DOE reviews over the past four years." Id. ¶ 5(b).

The Dahlstrom declaration also notes that the findings of the DOE Inspector General's report have been addressed:

> [7 of 8 findings] have been closed and validated by the NNSA Livermore Site Office. The eighth has been addressed and is awaiting closure at this moment. DOE security evaluation subsequent to the 2001 IG Report rated LLNL's security as "effective performance," the highest rating that can be received.

Id. ¶ 5(I).

The only question for the Court is whether the EA properly considered the security arrangements for the proposed BSL-3 facility. The Court admitted the Zipoli declaration not because it attempts to impugn DOE's competence generally, but because it could help the Court determine whether the EA appropriately considered the security information available to it—including perhaps any historical security failures that have occurred at LLNL.

The EA does not ignore the physical security of the LLNL buildings. While the EA notes that a security analysis will be conducted during the "project planning stage,"[4] it describes in detail the procedures according to which such plans will be developed and the regulations that will be followed:

> As in all facilities managed at LLNL, security in the proposed facility would be maintained by limiting access to only authorized DOE-badged personnel. Employee qualifications and training requirements are described in CDC-NIH guidelines . . . along with a discussion of appropriate management of security concerns.

LLNL AR1 at 17.

---

[3]The Dahlstrom declaration has two paragraphs numbered "5." Citations in this Order are to the one that appears first in the declaration.

[4]At the time that the EA issued, LLNL was not yet at the project planning stage.

Moreover, to the extent that security problems at LLNL represent a threat of large-scale release of biological contaminants, the broad "accident scenario" considered by the EA and discussed *supra* is applicable to *any* accidental release of hazardous materials, whether caused by natural disaster, accident, terrorist attack or sabotage. LLNL AR1 at 41, C-13. The EA further notes that the "uncertainty of available and viable microorganisms" makes LLNL an unlikely target for the theft of hazardous materials. LLNL AR1 at C-13.

In view of this analysis, the Court finds that Plaintiffs have not shown that the EA was arbitrary and capricious in its consideration of the environmental impact of physical-security issues at LLNL.

d. Problems with HEPA filtration

Plaintiffs argue that the EA's analysis overestimates the protective value of High Efficiency Particulate Air (HEPA) filters. HEPA filters are made from fiber materials and are designed to prevent the passage of 99.97% of particles of a specific size that hit the surface of the filters.

Plaintiffs argue, based on the declaration of an expert, that the EA's reliance on HEPA filters is misplaced. The expert, Marion Fulk, lists several particular problems with HEPA filters:

- HEPA filters are ineffective at capturing some dangerous organisms. Fulk Declaration ¶¶ 15-21.
- HEPA filters are prone to failure. In a survey of DOE facilities, 12% of a particular kind of HEPA filter were found to fail. *Id.* ¶ 13.
- Lab conditions leading to variations in air pressure, activation of fire-safety sprinklers, or the presence of heat, smoke, or fire can accelerate the failure of HEPA filters. *Id.* ¶¶ 13, 23.
- In the past, HEPA filters at LLNL have remained unchanged for more than 25 years. *Id.* ¶ 26.

However, despite having presented the opinions of a recognized expert, Plaintiffs have not established that the EA's analysis of HEPA filters was arbitrary or capricious. As with the other concerns raised by Plaintiffs, the question for this Court is not whether HEPA filters are reliable; the question is only whether the EA adequately analyzes the reliability of HEPA filters. The EA considers the particular problems with HEPA filters that the Fulk declaration notes, and it makes the following claims about HEPA

filters at the proposed BSL-3 facility:

- HEPA filters will be tested annually and replaced if necessary. LLNL AR1 at 43.
- Under the conditions that would prevail at the proposed BSL-3 facility, "there is no expectation that the HEPA filters would become moisture-saturated or torn—the two major reasons for HEPA filter failures." *Id.*
- Even if biological agents pass through HEPA filters, they are prone to destruction ("generally within minutes") by exposure to environmental factors such as UV light, dehydration, temperature, and oxygen. *Id.*
- In June 1999, LLNL adopted a policy requiring HEPA filters to be replaced within 10 years (or sooner under particular conditions). *Id.* at C-11.
- HEPA filters will be installed according to CDC/NIH criteria. *Id.*
- HEPA filters will be tested according to NSF standards. *Id.* at C-11 to C-12.

Even though the Fulk Declaration may have provided persuasive facts and opinions, the declaration does not undermine the reasonableness of the EA's assessment and plan. Thus, at most, Plaintiffs have noted a disagreement among experts, but as noted *supra*, "an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive." *Marsh*, 490 U.S. at 378.

2. Precedential effects

Before declining to issue an EIS, an agency must consider the extent to which a proposed action "may establish a precedent for future actions with significant effects" and whether it "represents a decision in principle about a future consideration." 40 C.F.R. 1508.27(b)(6). The Ninth Circuit has held that this regulation is designed to "avoid the thoughtless setting in motion of a 'chain of bureaucratic commitment that will become progressively harder to undo the longer it continues." *Presidio Golf Club v. National Park Serv.*, 155 F.3d 1153, 1162 (9th Cir. 1998).

Plaintiffs claim that the EA inadequately considers the precedential effects of the proposed BSL-3 laboratory—the first such laboratory at a DOE facility. Potential precedential effects fall into two chief categories:

(1) the operation of a BSL-3 facility at LLNL, a nuclear-research facility, could encourage

other nations to conduct biological research at nuclear facilities, leading to the risk of proliferation of weapons of mass destruction; and

(2) the operation of a BSL-3 facility at LLNL could encourage new similar facilities within the United States.

With respect to the first of these claims, Plaintiffs' argument fails for three reasons. First, the suggestion that the BSL-3 facility will provoke other nations into building their own facilities depends on a causal connection that is too speculative and remote. *See No Gwen Alliance, Inc. v. Aldridge*, 855 F.2d 1380, 1386 (9th Cir. 1988) (holding that an EA need not discuss speculative results like an increased probability of nuclear war); *Warm Springs Dam Task Force v. Gribble*, 621 F.2d 1017 (9th Cir. 1980) ("an impact statement need not discuss remote and highly speculative consequences") (citing *Trout Unlimited v. Morton*, 509 F.2d 1276 (9th Cir. 1974)). Second, as the Supreme Court has observed, the increased *risk* of an occurrence is not an *impact* on the environment under NEPA. *Metropolitan Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 775 (1983) (emphasis in the original). Third, the policy of foreign nations regarding weapons development is not an impact on the environment. *No GWEN Alliance v. Aldridge*, 855 F.2d 1380, 1386 (9th Cir. 1988) (holding that pursuant to NEPA an agency is not required to consider speculation about how United States defense policy will impact the foreign policy of foreign nations; "The nexus between construction of GWEN and nuclear war is too attenuated to require discussion in the environmental impact statement"). "Neither the language nor the history of NEPA suggest that it was intended to give citizens a general opportunity to air their policy objections to proposed federal actions. The political process and not NEPA, provides the appropriate forum in which to air policy agreements." *Metropolitan Edison*, 460 U.S. at 777.

With respect to the second claim, Plaintiffs' argument that the proposed facility could encourage similar facilities overstates the importance of the individual facility proposed. Many similar facilities already exist, including those at the San Francisco and Davis campuses of the University of California. Plaintiffs argue that the proposed facility is unique because it will "weaponize" pathogens; however, Plaintiffs support this point only by using stricken declarations, and the EA directly contradicts it. *See* LLNL AR1 at C-7 (noting that LLNL will not "weaponize" pathogens and that weaponization is not part of any DOE proposal). Plaintiffs have not demonstrated that this claim by the EA is arbitrary or not credible.

Moreover, as Defendants note, the environmental effects of all future facilities that the DOE proposes will be subject to the same analysis under NEPA that was necessary for the LLNL facility. In view of this continuing requirement, Plaintiffs have not demonstrated that the operation of the proposed BSL-3 facility involves the "thoughtless setting in motion of a 'chain of bureaucratic commitment.'" *Presidio Golf Club*,155 F.3d at 1162.

3. Public controversy

Under 40 C.F.R. 1508.27(b)(4), the EA must consider "the degree to which the effects on the quality of the human environment are likely to be highly controversial." To establish the type of controversy requiring the preparation of an EIS, there must be a "substantial dispute" over the size, nature or effect" of the proposal. *Foundation for N. Am. Wild Sheep v. USDA*, 681 F2d 1172, 1182 (9th Cir. 1982). For example, in *Foundation*, controversy existed not because the majority of public comments opposed the project, but because the comments of scientists and state wildlife agencies created substantial dispute over the scientific conclusions of the USDA. Id.

Plaintiffs argue that the DOE must prepare an EIS because the DOE, during the public comment period, received numerous comments opposing the operation of a BSL-3 facility at LLNL. Defendants note, however, that out of the 83 comments DOE received, 73 were copies of a chain letter drafted by one of this case's Plaintiffs. Thus, only a relatively small number of individuals have voiced objections, and some of these objections are only political in nature and do not directly discuss why the environmental effect of the lab is, itself, controversial.[5] It is likely that genuine political or moral beliefs motivated these letters, but the letters do not explain why the "*effects on the quality of the human environment* are likely to be highly controversial." 40 C.F.R. 1508.27(b)(4) (emphasis added).

Moreover, the EA considers and responds to the comments the DOE received. *See* LLNL AR1 app C. 21. For example, DOE responded to comments regarding the risks posed by transportation of infectious agents to and from the BSL-3 facility. The EA explains that shipments of agents to LLNL would

[5]For instance, one comment begins, "I don't want my tax dollars used for a BSL-3 facility run by the DOE. Why isn't the CDC handling this research? They appear to be more qualified than the Livermore Lab." LLNL AR1 at C-20. Another reads, "We have enough of these labs already. How about looking for ways to advance & evolve all people in ways of peace instead of subjugation & threats." *Id.* at C-32.

be small in size, typically around one milliliter (a milliliter is about one-fifth of a teaspoon). AR 1:1:22, C-13. Each shipment must be packaged according to Department of Transportation (DOT) regulations at 49 C.F.R. Pt. 171-178; AR 1:1:23. Each shipment is also subject to regulations of the U.S. Public Health Service (42 C.F.R. Pt. 71-73), the Department of Agriculture (7 C.F.R. Pt. 330-331 and 9 C.F.R. Pt. 92), and the Postal Service (39 C.F.R. Pt.111). AR 1:1:22.

Plaintiffs do not suggest that DOE was *unaware* of the public comments. *See Surfrider Found. v. Dalton*, 989 F. Supp. 1309, 1322 (S.D. Cal. 1998) (government's point by point answers demonstrate that agency considered public controversy); *Northwest Envtl. Defense Ctr. v. Wood*, 947 F.Supp. 1371 (D.Or.1996) ("It is, nonetheless, true that private citizens, both scientists and non-scientists, argued against issuance of the permit. . . . As indicated above, the Corps addressed these concerns. Moreover, the Corps ultimately stated that its decision was consistent with the views of 'numerous commenters' that 'sufficient laws, regulations, codes and programs exist to ensure sufficient environmental protection. . . .' The Corps concluded, 'although the project remains controversial in the community, the probability of other than non-significant impacts occurring is extremely low.'") (citations omitted).

As the Fourth Circuit has warned, if the environmental effects of a proposed action must be treated as "controversial" merely because the action is opposed, "opposition, and not the reasoned analysis set forth in an environmental assessment, would determine whether an environmental impact statement would have to be prepared. The outcome would be governed by a 'heckler's veto.'" *North Carolina v. FAA*, 957 F.2d 1125, 1133-34 (4th Cir. 1992) (citations omitted).

Moreover, the expert declarations submitted as part of Plaintiffs' motion for summary judgment and opposition to Defendants' motion for summary judgment—which were filed after the EA was issued—cannot be taken to demonstrate a controversy. "We cannot characterize an agency's action as 'arbitrary' for its failure to consider views that were never presented to it." *Greenpeace Action v. Franklin*, 982 F.2d 1342, 1353 n.12 (9th Cir. 1992).

4. Cumulative effects

Under 40 C.F.R. 1508.27(b), the EA must consider "[w]hether the action is related to other actions with individually insignificant but cumulatively significant impacts." A cumulative impact is one "which results from the incremental impact of the action when added to other past, present, and reasonably

foreseeable future actions." 40 C.F.R. 1508.7.

Plaintiffs argue that the EA's consideration of the cumulative environmental effects of the proposed BSL-3 facility was inadequate. However, it is not clear what specific argument Plaintiffs raise to question the EA's consideration of cumulative effects. *See* LLNL AR1 at 56. Instead, Plaintiffs seem to merge this argument into claims about precedential effects, claims about the relevance of the CBNP, and claims about the interaction between the proposed BSL-3 facility and the existing BSL-1 and BSL-2 facilities at LLNL. The Court has already held that DOE's decisions regarding these issues were not arbitrary or capricious. For the same reasons, discussed *supra*, the Court finds that the EA adequately considers the cumulative effects of the proposed BSL-3 facility. For example, the EA considers the cumulative effect of the hazardous waste that will be generated by the existing BSL-1 and BSL-2 facilities with the proposed BSL-3 facility. In 2002 LLNL generated approximately 658,000 lbs of solid hazardous waste. AR1:27:7-2. The proposed BSL-3 lab will generate an additional 1,144 lbs of solid waste. This is an insignificant increase; thus, the cumulative effect is minimal.

C. Plaintiffs' challenge against DOE's decision not to file a PEIS for the NNSA's CBNP

The EA under consideration in this case concerns the single proposed BSL-3 facility at LLNL. The DOE produced a separate EA for a similar proposed facility at LANL. Plaintiffs argue that the NNSA's nationwide Chemical and Biological National Security Program (CBNP) proposes connected, cumulative action that requires a single Programmatic EIS (PEIS); alternatively, they argue that at least the proposed BSL-3 facilities at LLNL and LANL should be treated by a single EIS.

Regulations promulgated under NEPA define the appropriate scope for EA and EIS documents. Under 40 C.F.R. 1508.25, for example, agencies must consider whether multiple proposed actions are connected or whether they automatically trigger new actions, and agencies must account for such connections. The decision of whether to prepare a PEIS is subject to the same "arbitrary and capricious" standard that governs the rest of this APA review. *See Churchill County v. Norton*, 276 F.3d 1060, 1075 (9th Cir. 2001) ("a party challenging an agency's refusal to prepare a comprehensive EIS must show that the agency acted arbitrarily in making that determination"). Regulations suggest that "agencies may find it useful" to choose a scope based on "one of the three following ways: . . . (1) Geographically . . . (2)

Generically**,** including actions which have relevant similarities, including common timing, impacts, alternatives, methods of implementation, media, or subject matter. . . . (3) By stage of technological development." 40 C.F.R. 1502.4.

Generally, the regulations are deferential to the agency. They state that "agencies *may find it useful*" to choose a scope based on one out of three standards (one of which includes geography). C.F.R. 1502.4. In some circumstances, the Ninth Circuit has found that a single EIS or PEIS must be conducted because the projects have are intertwined and have a cumulative effect. To illustrate, in *Thomas v. Peterson*, 753 F.2d 754, 759-760 (9th Cir.1985), the Ninth Circuit required a single EIS where it found sufficient evidence in the record to suggest that road and timber sales would have significant cumulative effects, including sediment deposits in the Salmon River (detrimental to fish) and destruction of critical habitat for the endangered Rocky Mountain gray wolf. In *City of Tenakee Springs v. Clough*, 915 F.2d 1308, 1312 (9th Cir.1990), the Ninth Circuit held that an agency must prepare both a programmatic EIS and a site-specific EIS "[w]here there are large scale plans for regional development." *Id.* Notably, in each case, the programs were intertwined because they affected the same geographic region. Thus, at least when the projects in a particular geographical region are foreseeable and similar, NEPA may call for an examination of their impact in a single EIS. In the case at hand, however, LANL and LLNL are two distinct facilities. They are located in separate states. Plaintiffs have not demonstrated that the building of these two facilities is so intertwined that their impacts should have been analyzed together. For example, a catastrophic accident at the LANL facility in New Mexico will not affect the environment where LLNL is located, California. Nor are the facilities interdependent such that what occurs within LANL will dictate what occurs within LLNL or vice versa. Moreover, there are over 250 BSL-3 facilities within the United States, including one at the University of San Francisco campus and one at the University of California Davis campus. Given the number of facilities, it is doubtful that the addition of two more facilities in separate geographic locations would provide a cumulative impact. Thus, Plaintiffs have not demonstrated that DOE's decision to issue separate EAs for these separate facilities was arbitrary or capricious.

D. Plaintiffs' challenge against DOE's decision not to file a PEIS examining the combined effects of the proposed BSL-3 facility and the existing BSL-1 and BSL-2 facilities at LLNL

The regulations define "cumulative actions" as those which "when viewed with other *proposed*

actions have cumulatively significant impacts." 40 C.F.R. § 1508.25(a)(2) (emphasis added). A PEIS is required for proposed projects, not existing ones. *Andrus v. Sierra Club*, 442 U.S. 347, 350, 355 (1979), *Kleppe v.Sierra Club*, 427 U.S. 390, 415 (1976).

Plaintiffs argue that DOE should have filed a PEIS to examine the effects that the proposed BSL-3 lab will have when combined with the BSL-1 and BSL-2 facilities at LLNL. The BSL-1 and BSL-2 facilities, however, are not "other proposed actions." They are existing facilities that have already been subject to review under NEPA. Thus, they cannot constitute "cumulative actions."

Moreover, the EA considers the effect that the BSL-3 lab will have and concludes that it will not result in a cumulatively significant impact. AR 1:1:56. The existing BSL-1 and BSL-2 labs handle materials that pose, at most, a "moderate hazard" and have a two decade history of safe operation. Although Plaintiffs dispute these findings and proffer the declarations of numerous experts in support of their claim, the Court must defer to DOE's discretion in choosing and relying upon the reasonable findings of its own experts. As discussed *supra* Defendants have chosen to rely on their own experts, which they have the discretion to do; Defendants have established that their experts dispute the scientific findings of Plaintiffs' experts; Defendants have demonstrated that the grounds for Defendants' experts findings were reasonable (e.g., the choice of Q Fever as the test agent was supported by the CDC); and thus the record establishes that DOE took the required "hard look." While Plaintiffs may strenuously object to DOE's findings, they have not shown that DOE's assessments are arbitrary or capricious.

E. Summary

Because the record demonstrates that DOE took the requisite hard look and that its conclusions were not arbitrary or capricious, Defendants are entitled to summary judgment on the issue of the adequacy of the EA.

PLAINTIFFS' CLAIMS UNDER FOIA

A. Standard of review

Summary judgment for the defending agency is appropriate in a FOIA case if the agency can demonstrate that it has "conducted a search reasonably calculated to uncover all relevant documents." *Weisberg v. United States Dep't of Justice*, 705 F.2d 1344, 1351 (D.C.Cir.1983); *see also Zemansky v. United States EPA*, 767 F.2d 569, 571 (9th Cir.1985). The defending agency bears the burden of

proving the adequacy of the search. *Carney v United States Dep't of Justice*, 19 F.3d 807, 812 (2nd Cir.1994); *Weisberg*, 705 F.2d at 1350. The court views the facts, and all reasonable inferences therefrom, in the light most favorable to the requester. *Zemansky*, 767 F.2d at 571; *Pollack v. United States Bureau of Prisons*, 879 F.2d 406, 409 (8th Cir.1989).

To prevail, the defendant agency must demonstrate that the search was adequate. *Zemansky*, 767 F.2d at 571. This inquiry depends on whether the search was reasonable under the facts of the case. *Id*. The agency must show only that the search was reasonable, not that it was exhaustive or that every document has been located. *Miller v. United States Dep't of State*, 779 F.2d 1378, 1383 (8th Cir.1985); *Zemansky*, 767 F.2d at 571. The agency "must make a diligent search for the requested documents in the places in which they might be expected to be found." *Chamberlain v. United States Dep't of Justice*, 957 F.Supp. 292, 294 (D.D.C.1997).

The agency may satisfy its burden by providing "reasonably detailed, nonconclusory affidavits submitted in good faith." *Zemansky*, 767 F.2d at 571; *see also Carney*, 19 F.3d at 812. At a minimum, the affidavits or declarations should provide detail about the method and scope of the search. *Maynard v. CIA*, 986 F.2d 547, 559 (1st Cir.1980). Affidavits or declarations submitted by an agency are " 'accorded a presumption of good faith." *Carney*, 19 F.3d at 812 .

If the agency has provided the required affidavits, the burden shifts to the requester to raise a material factual issue concerning the reasonableness of the search. *Miller*, 779 F.2d at 1384. This can be done by "contradicting the [agency's] account of the search procedure or by raising evidence of the [agency's] bad faith." *Id* .; *see also Carney*, 19 F.3d at 812.

B. Discussion

The parties do not dispute that DOE has provided to Plaintiffs all non-privileged documents in its possession that are responsive to (1) Plaintiffs' two September 23, 2002 FOIA requests, see Pelzner-Goodwin Declaration; Becknell Declaration; Weisse Declaration, (2) Plaintiffs' two May 19, 2003 FOIA requests, see Lopez Declaration, Pelzner-Goodwin Declaration, Withnell Declaration, and (3) Plaintiffs' March 10, 2003 FOIA request, see Rothrock Declaration. Plaintiffs argue, however, that DOE's responses were untimely. DOE provided many of the documents only after litigation had commenced; Plaintiffs argue this untimeliness is evidence of bad faith.

Generally, a lack of timeliness does not preclude summary judgment for an agency in a FOIA case. *Papa v. U.S.*, 281 F.3d 1004 (9th Cir. 2002) (production of all nonexempt material, "however belatedly," moots FOIA claims); *Minier v. CIA*, 88 F.3d 796, 803 (9th Cir.1996) (rejecting claim of bad faith where agency took over two years to answer FOIA request); *Carney*, 19 F.3d at 812-13 (2nd Cir.1994); *Hornbostel v. U.S. Dept. of Interior*, 305 F. Supp. 2d 21, 25 (D.D.C.,2003); *Landmark Legal Foundation v. E.P.A.*, 272 F. Supp. 2d 59, 61 (D.D.C.,2003). The only question for summary judgment is whether the agency finally conducted a reasonable search, and whether its withholdings (if in dispute) are justified. When exactly a reasonable search was conducted is irrelevant. See, e.g., *Hornbostel*, 305 F. Supp. 2d at 25; *Atkins v. Dep't of Justice*, 1991 WL 185084 (D.C.Cir. Sept.18, 1991) (unpub.) ("The question whether DEA complied with the Freedom of Information Act's (FOIA) time limitations in responding to Aaron Atkins' request is moot because DEA has now responded to this motion."); *Tijerina v. Walters*, 821 F.2d 789, 799 (D.C.Cir.1987) (" '[H]owever fitful or delayed the release of information under the FOIA may be ... if we are convinced appellees have, however belatedly, released all nonexempt material, we have no further judicial function to perform under the FOIA.' ") (quoting *Perry v. Block*, 684 F.2d 121, 125 (D.C.Cir.1982)).

When a plaintiff argues that an agency's untimeliness is due to bad faith, courts may look at whether it appears that the agency noticeably stepped up its cooperative efforts subsequent to the filing of the suit. If some essentially insignificant documents were released before the lawsuit but significantly more were released due to the lawsuit, the plaintiff has substantially prevailed. "Normally, the rate of document production before and after filing a complaint is probative as to whether litigation had a significant effect on an agency's response." *O'Neill, Lysaght & Sun v. Drug Enforcement Admin.* 951 F.Supp. 1413, 1420 (C.D.Cal.,1996) (internal citations omitted).

In support of their allegation of DOE's bad faith, Plaintiffs lists examples of what they perceive as DOE's untimely responses. DOE did not release a final determination regarding Plaintiff Nuclear Watch New Mexico's September 23, 2002 FOIA request (FOIA #02-79-C) until February 18, 2004, the same day plaintiffs filed their Motion for Summary Judgment. DOE did not release a final determination regarding

Plaintiff Tri-Valley CAREs' May 19, 2003 FOIA request (FOIA #2003-OK-20) until March 4, 2004, ten months after the request was made. DOE did not release a final determination regarding Plaintiff Nuclear Watch New Mexico's September 23, 2002 FOIA request to DOE-Oakland ("DOE-OK") (FOIA #2002-OK-49) until February 9, 2004 and March 12, 2004, over sixteen months after the request had been made.

At the outset, the Court notes that the earliest of these requests was filed on September 23, 2002. Plaintiffs commenced the underlying litigation almost a year later, on or about September 16, 2003. Once litigation commenced, for litigation purposes, the documents responding to the FOIA requests had to be reviewed by DOE headquarters before they were released. (Pelzner Decl. ¶ 6.) Thus, the delays that arose after September 2003 are due, at least in part, to the need for DOE headquarters' review; such delays do not evidence bad faith.

Moreover, in response to Plaintiffs' allegations of bad faith, DOE has submitted detailed declarations explaining the processing of Plaintiffs' FOIA requests. For example, Roseann Pelzner, a FOIA Officer in the Oakland Operations Office of DOE, explains that upon receipt of the September 23, 2002 FOIA request from Nuclear Watch New Mexico, she coordinated the document search with LLNL. (Pelzner Decl. ¶ 6.) She analyzed the FOIA request for a fee waiver and then forwarded the request to LLNL for an estimate of the cost of production of the documents. (Id.) When she received a request for a response from Nuclear Watch New Mexico on November 18, 2002, she responded within three days by advising Nuclear Watch New Mexico that "[a]s any document would have to be reviewed by Headquarters prior to release, I was not able to estimate the time required to respond fully, but I assured the requester that the request was being processed as promptly as possible) (Id.) Thus, the delay was not

due to DOE's bad faith, but rather DOE's attempt to search documents with LLNL and have those documents approved by headquarters.

With respect to the May 22, 2003 FOIA request from Tri-Valley CAREs, Ms. Pelzner declares that after investigation, she determined that DOE-OAK and LLNL had no documents responsive to Plaintiffs' requests. She transferred the request to Headquarters, as required by DOE regulations. In addition, within five days of receiving the FOIA request, Ms. Pelzner notified Tri Valley CAREs of the results of her investigation.

In addition, Carolyn Becknell, a FOIA Officer with DOE in Albuquerque, New Mexico describes a detailed review of voluminous documents. Ms. Becknell reviewed Plaintiff Nuclear Watch New Mexico's FOIA request of September 23, 2002. (Becknell Decl. ¶ 5.) Upon receipt, Ms. Becknell contacted the BSL technical person in Albuquerque, who advised her that the request should be transferred to DOE Headquarter for action. (Id. ¶ 6.) Ms. Becknell forwarded the request to Abel Lopez, Director, FOIA and Privacy Act Group, Headquarters for DOE; she informed Nuclear Watch New Mexico that she had done so. (Id.) On November 1, 2002, Mr. Lopez issued a memorandum stating that DOE had sent to Nuclear Watch New Mexico documents responsive to item 1(f) of the request. (Id. ¶ 7.) Ms. Becknell had to track the records down, as they originated from a number of offices including DOE's Los Alamos Site Office, Sandia National Laboratories, and LANL. (Id. ¶ 8.) She began tracking them down on or about November 7, 2002. By November 3, 2003, LANL had found 62 responsive records and forwarded them to Ms. Becknell. The Los Alamos Site Office had found 29 responsive records and forwarded them to her. Ms. Becknell then forwarded the records for review by DOE Headquarters and the Department of Homeland Security. Once the records were approved for release, Ms. Becknell

forwarded them to Plaintiffs on February 18, 2004.

While Ms. Becknell's response to the FOIA request was indeed time consuming, the Court does not find that it reflects bad faith. Instead, it reflects the time that it takes to collect and get approval for potentially sensitive records located in multiple sites. Given that the records involve information regarding BSL-3 laboratories, which require review from Homeland Security, the delay is understandable.

Plaintiffs also argue that DOE improperly withheld documents requested by Tri-Valley CAREs. On May 19, 2003, Tri-Valley CAREs requested "all memoranda of agreement (MOA's) and memoranda of understanding (MOU's) that have been concluded between the DOE and the CDC or its parent agency for access, use or activities at any other BSL-3 or BSL-4 facilities in the U.S. . . . Any other documents in the possession of DOE, LLNL or LANL that discuss or establish practices or procedures for BSL-2, BSL-3, or BSL-4 activities at a CDC owned or operated facility." (Declaration of Pelzner Goodwin, Exhibit E to DCM, page 2.)

While DOE did not produce any MOU's in response to this request, on January 29, 2004, DOE released an MOU between LLNL and the CDC to Nuclear Watch of New Mexico. Plaintiffs argue that that MOU should have been released to Tri-Valley CAREs pursuant to its May 19, 2003 FOIA request, as it was an MOU between a DOE National Laboratory and the CDC. Plaintiffs argue that the fact that it was not sent in response to that request demonstrates that the DOE office handling the request did not make its required "good faith" effort to conduct a search for the requested records. The issue before this Court, however, " is not whether there might exist any other documents possibly responsive to the request, but rather whether the search for those documents was adequate." *Citizens Comm'n On Human Rights v. FDA*, 45 F.3d 1325, 1328 (9th Cir. 1995)(internal quotes omitted). Given the detailed response set forth

by Ms. Pelzner regarding the search she conducted, the absence of this one document does not evidence bad faith.

Because: (1) DOE has set forth detailed facts regarding the searches it undertook to respond to Plaintiffs' FOIA requests; (2) Plaintiffs have failed to show that the searches themselves were inadequate; and (3) DOE has set forth detailed facts regarding why its responses took a number of months, and Plaintiffs have not demonstrated that the delay was due to bad faith, Defendants are entitled to summary judgment on the FOIA issue.

CONCLUSION

Based on the foregoing,

IT IS HEREBY ORDERED THAT Defendants' motion for summary judgment is GRANTED; Plaintiffs' motion for summary judgment is DENIED. The Clerk of the Court shall terminate the file.

IT IS SO ORDERED.

Dated: September 10, 2004

/s/ Saundra Brown Armstrong
SAUNDRA BROWN ARMSTRONG
United States District Judge

EXHIBIT 3

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

FILED

OCT 16 2006

CATHY A. CATTERSON, CLERK
U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

TRI-VALLEY CARES et al., Plaintiffs - Appellants, v. DEPARTMENT OF ENERGY et al., Defendants - Appellees.	No. 04-17232 D.C. No. CV-03-03926-SBA MEMORANDUM[*]

Appeal from the United States District Court
for the Northern District of California
Saundra B. Armstrong, District Judge, Presiding

Argued and Submitted June 13, 2006
San Francisco, California

Before: SCHROEDER, Chief Judge, GRABER, Circuit Judge, and HOLLAND,[**] Senior District Judge.

Plaintiffs Tri-Valley Cares, Nuclear Watch of New Mexico, and individuals (collectively, "Tri-Valley") appeal the district court's order granting summary judgment in favor of Defendants United States Department of Energy and its

---

[*] This disposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as provided by 9th Cir. R. 36-3.

[**] The Honorable H. Russel Holland, United States District Judge for the District of Alaska, sitting by designation.

auxiliaries (collectively, "DOE"). On appeal, Tri-Valley makes three specific arguments concerning the proposed construction of a federal government biological weapons research laboratory near San Francisco. First, Tri-Valley asserts that the DOE failed to comply with the National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321-4370 ("NEPA"), by issuing a Finding of No Significant Impact ("FONSI") after analyzing the project in an Environmental Assessment. According to plaintiffs, the proposed research laboratory may have a significant effect on the human environment and, accordingly, the DOE must prepare an Environmental Impact Statement. Second, Tri-Valley claims that, under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), DOE failed timely to provide non-exempt documents. Third and finally, plaintiffs claim that the district court improperly struck portions of plaintiffs' extra-record declarations. We review a district court's grant of summary judgment upholding an agency decision de novo. Natural Res. Def. Council v. U.S. Dep't of Interior, 113 F.3d 1121, 1123 (9th Cir. 1997).

1. If an Environmental Assessment demonstrates that substantial questions are raised about the environmental effects of a proposed agency action, a FONSI may not be issued and the agency must prepare a full Environmental Impact Statement. Found. for N. Am. Wild Sheep v. U.S. Dep't of Agric., 681 F.2d 1172,

1178 (9th Cir. 1982). Plaintiffs challenge the DOE's Environmental Assessment due to its alleged failure to assess fully and correctly potentially significant effects on public health and safety (such as fire, earthquake, and terrorist attacks), uncertain effects posing substantial risks, significant precedential effects, significant cumulative effects, and public controversy.

Review of agency action under the Administrative Procedure Act, 5 U.S.C. § 706(2), is "highly deferential." Friends of the Earth v. Hintz, 800 F.2d 822, 831 (9th Cir. 1986). Although Tri-Valley raised some substantial questions about the validity of DOE's substantive conclusions,[1] this court may not substitute its judgment for the reviewing agency's. Laguna Greenbelt, Inc. v. U.S. Dep't of Transp., 42 F.3d 517, 523 (9th Cir. 1994) (per curiam). NEPA is a procedural statute that "'does not mandate particular results,' but 'simply provides the necessary process' to ensure that federal agencies take a 'hard look' at the environmental consequences of their actions." Muckleshoot Indian Tribe v. U.S. Forest Serv., 177 F.3d 800, 814 (9th Cir. 1999) (per curiam) (quoting Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350 (1989)). With the exception of the lack of analysis concerning the possibility of a terrorist attack, we hold that

[1] We note in particular the DOE's minimal assessment of earthquake risks despite the presence of known, active faults that run directly under nearby Berkeley/Alameda County, California.

the DOE did take a "hard look" at the identified environmental concerns and that the DOE's decision was "fully informed and well-considered." Save the Yaak Comm. v. Block, 840 F.2d 714, 717 (9th Cir. 1988) (internal quotation marks omitted).

Concerning the DOE's conclusion that consideration of the effects of a terrorist attack is not required in its Environmental Assessment, we recently held to the contrary in San Luis Obispo Mothers for Peace v. Nuclear Regulatory Commission, 449 F.3d 1016 (9th Cir. 2006). In Mothers for Peace, we held that an Environmental Assessment that does not consider the possibility of a terrorist attack is inadequate. Id. at 1035. Similarly here, we remand for the DOE to consider whether the threat of terrorist activity necessitates the preparation of an Environmental Impact Statement. As in Mothers for Peace, we caution that there "remain open to the agency a wide variety of actions it may take on remand [and] . . . [w]e do not prejudge those alternatives." Id.

2. Plaintiffs requested many documents pursuant to FOIA, and all of the requested documents have been produced. Eventual production, "however belatedly, moots FOIA claims." Papa v. United States, 281 F.3d 1004, 1013 (9th Cir. 2002) (internal quotation marks omitted). No exception to the mootness doctrine applies because there is no evidence of bad faith or a recurring pattern of

FOIA violations by the DOE. See generally Biodiversity Legal Found. v. Badgley, 309 F.3d 1166, 1174 (9th Cir. 2002) (holding that an agency which exhibited a recurring pattern of correcting regulatory violations immediately after the commencement of litigation could be challenged, as an exception to the mootness doctrine). The district court properly concluded that the DOE's response to Tri-Valley's FOIA requests was adequate, see Zemansky v. EPA, 767 F.2d 569, 571 (9th Cir. 1985) ("In demonstrating the adequacy of the search, the agency may rely upon reasonably detailed, nonconclusory affidavits submitted in good faith."), and that the often considerable delay was not due to bad faith.

3. The district court did not abuse its discretion by excluding certain extra-record declarations submitted by Tri-Valley. See Sw. Ctr. for Biological Diversity v. U.S. Forest Serv., 100 F.3d 1443, 1447 (9th Cir. 1996) (holding that a district court's decision to exclude extra-record evidence is reviewed for abuse of discretion). Judicial review of agency action is generally limited to review of the administrative record, 5 U.S.C. § 706; Animal Def. Council v. Hodel, 840 F.2d 1432, 1436 (9th Cir. 1988), and extra-record materials are allowed only in certain circumstances, Sw. Ctr., 100 F.3d at 1450 (describing the four categories of circumstances). The district court, after conducting a thorough and detailed analysis of each of the fifteen declarations submitted by Tri-Valley, allowed three

declarations in whole and four declarations in part, and excluded eight declarations. The district court found that the excluded declarations contained impermissible legal conclusions, opinions from lay witnesses, or political statements; raised only remote and highly speculative consequences, Presidio Golf Club v. Nat'l Park Serv., 155 F.3d 1153, 1163 (9th Cir. 1998); improperly raised information that became available after the agency decision-making process, Northcoast Envt'l Ctr. v. Glickman, 136 F.3d 660, 665 (9th Cir. 1998); or were cumulative, id. The district court properly excluded the declarations based on these legally valid reasons and therefore did not abuse its discretion.

AFFIRMED in part, REVERSED in part and REMANDED for further action consistent with this decision. The parties shall bear their own costs on appeal.

EXHIBIT 4

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

U.S. Department of Energy
Revised Finding of No Significant Impact
for the Biosafety Level 3 Facility
at Lawrence Livermore National Laboratory

AGENCY: U.S. Department of Energy

ACTION: Finding of No Significant Impact

SUMMARY: An Environmental Assessment (EA) and a Finding of No Significant Impact for a proposed BSL-3 facility was issued in December 2002 (BSL-3 EA, DOE/EA-1442), and construction of the facility began. On September 16, 2003, Tri-Valley CARES filed a lawsuit in the federal district court in San Francisco challenging the adequacy of the EA for the proposed BSL-3 facility. On September 10, 2004, the district court found the EA to be adequate. On November 8, 2004, Tri-Valley CARES filed a notice of appeal with the Ninth Circuit Court of Appeals. On October 16, 2006, the appellate court issued a memorandum opinion (D.C No CV-03-03926-SBA). In light of the Ninth Circuit's recent ruling in an unrelated case, the court remanded the matter for DOE to consider whether the threat of potential terrorist activity necessitates the preparation of an environmental impact statement.

The U.S. Department of Energy (DOE) has prepared a Revised Environmental Assessment (EA), DOE/EA-1442R, to assess the potential environmental impacts associated with the construction and operation of the proposed Biosafety Level 3 Facility (BSL-3) at the Lawrence Livermore National Laboratory (LLNL) in Livermore, California, including those impacts potentially associated with terrorist activities.

DOE became involved in bioscience work in support of its biology and biotechnology research programs, work for other agencies, and work in support of the Chemical and Biological National Security Program (CBNP). The National Nuclear Security Administration's CBNP mission was to "develop, demonstrate and deliver technologies and systems to improve domestic defense capabilities and, ultimately, to save lives in the event of a chemical or biological attack." Since this EA was originally published, many of DOE's missions relating to biological security have been transferred to the Department of Homeland Security (DHS) by the Homeland Security Act of 2002. The Act authorizes DHS to access the capabilities of DOE's laboratories and other sites to further DHS mission objectives. As a result, DOE and Lawrence Livermore National Laboratory continue to support this mission by performing work for the DHS on a "work for others" basis.

In order to meet these mission requirements, it is necessary to expand some existing capabilities to test the understanding and effectiveness of research on infectious agents and biotoxins, particularly those associated with potential bioweapons threats. Efficient execution of the mission, therefore, also requires the capability to handle operations

involving rodent challenges of bioagents (and possibly biotoxins) and the ability to produce small amounts of biological material (enzymes, DNA, ribonucleic acid [RNA], etc.) using infectious agents and potentially, genetically modified agents under conditions that would require management of a facility at the BSL-3 level.

An on-site BSL-3 facility would provide safe and secure handling and storage of infectious microorganisms at a time when these issues are imperative to national security research. In order to more effectively utilize and capitalize on existing onsite facilities and capabilities at LLNL, including informatics and DNA sequencing capability, and to ensure the quality, timeliness, integrity and security of microbiological work, NNSA needs BSL-3 laboratory capability within the boundaries of this national laboratory.

The proposed facility would include three BSL-3 laboratory rooms, one of which would be capable of holding rodents. The building would include clothes-change and shower rooms, a mechanical room, and some storage space, but no office space. When complete, the BSL-3 facility would be about 1,500 ft^2 (135 m^2) in size. The operational design life of the proposed facility would be at least 30 years.

No significant environmental impacts are expected as a result of the proposed action. Site preparation and construction impacts associated with the proposed action have already occurred.. The potential environmental consequences from routine operation would be minor and would not differ greatly between the Proposed Action and alternatives. By adopting the guidelines established mutually by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) as standards, the potential human health effects of operating the proposed BSL-3 laboratory would be very low, as have been those demonstrated for operating similar existing CDC-registered laboratories that are required to implement the same guidelines. Relevant human health information indicates that laboratory-acquired or laboratory-associated infections should be considered abnormal events due to their infrequency of occurrence. No cases of illness would be expected to result from implementing the Proposed Action.

All room air used within the facility would be doubly HEPA-filtered before release. Such air emissions from the facility would not result in any significant human health or environmental impact. There would be no radionuclides and no chemicals present in the facility other than routine industrial cleaners and process chemicals. As a result, no significant quantities of such materials that could adversely impact human health or the environment would be susceptible to release in the event of an accident. Liquid biological-material wastes to be released from the proposed facility to the sanitary sewer would not be hazardous and would not require any upgrade to the sewer system or the Livermore Water Reclamation Plant (LWRP). Such liquid wastes would be first autoclaved or chemically disinfected before release to the sanitary sewer system. Construction activities would not occur at a depth at which finding of cultural or paleontological resources would be anticipated. Furthermore, no significant cumulative impacts or environmental justice issues are expected.

On September 16, 2003, suit was filed in federal district court challenging the adequacy of the prior version of this EA. The district court ruled that the EA was adequate and plaintiffs appealed to the Ninth Circuit. In October 2006, the appellate court issued its decision. It concluded that while NNSA did take a hard look at identified environmental concerns and that its decision was fully informed and well-considered, the NNSA had not considered whether the threat of potential terrorist activity necessitated the preparation of an environmental impact statement. The Court therefore remanded the matter to NNSA.

In accordance with the Ninth Circuit's remand, NNSA has reviewed the threat to the facility from terrorists and the potential environmental effects that might derive from various terrorist acts against the facility. This review finds that, because of the extensive layered security programs at the LLNL, no environmental impacts are expected as a result of potential terrorist activities directed against this facility.
Based on the analysis in the EA and considering public comment, DOE/NNSA has determined that the proposed action does not constitute a major federal action significantly affecting the quality of the human environment within the meaning of the *National Environmental Policy Act of 1969*, 42 U.S.C. 4321 et seq. Therefore, preparation of an Environmental Impact Statement is not required and DOE/NNSA is issuing this notice of Finding of No Significant Impact (FONSI).

PROPOSED ACTION: DOE proposes to construct and operate a new facility, the Biosafety Level 3 (BSL-3) Facility, at LLNL. The proposed facility would be approximately 1,500-ft^2 located near the center of the LLNL Livermore site.

The proposed facility would consist of a one-story permanent prefabricated BSL-3 laboratory facility assembled on-site, which would have three individual BSL-3 laboratory rooms (one of which would be capable of holding rodents), a mechanical room, clothes-change and shower rooms, and small storage space. The building footprint would take less than one-quarter acre. It is estimated that the operational design life of the proposed building would be at least 30 years. The proposed action would include minor modifications to existing parking areas and site landscaping.

The Proposed Action and its alternatives differ mainly in how the facility would be constructed. The BSL-3 facility would be designed and operated in accordance with guidance for BSL-3 laboratories established by the CDC and the NIH. Physical security would be implemented commensurate with the level of work being performed within the facility. No radiological, high explosives, or propellant material would be used or stored in the proposed BSL-3 facility. The proposed facility would have a capability to perform small-volume aerosol challenges of rodents, using infectious agents or biologically derived toxins (biotoxins). Sample shipments would be received only in compliance with all established Department of Transportation (DOT) and CDC shipping guidelines and requirements. The samples would be stored in the BSL-3 laboratory within a locked, labeled freezer or refrigerator according to the needs of the sample for preservation. Biological wastes would be disposed of in accordance with CDC and NIH guidance, and other applicable federal, state, and local regulations.

ALTERNATIVES: Three alternatives to the Proposed Action were considered and discussed in the EA.

- The No-Action Alternative
- Construct and Operate an On-Site-Constructed BSL-3 Facility
- Remodel/Upgrade a Single-Room Laboratory in Building 365 to BSL-3

Three other alternatives were considered in the EA, but were eliminated from detailed analysis for a number of reasons.

- Construction and Operation of the Proposed BSL-3 Facility at Another Main Site LLNL Location
- Construction and Operation of the Proposed BSL-3 Facility at Site 300
- Construction and Operation of the BSL-3 Facility at Another National Security Laboratory

No-Action Alternative. Under the No Action Alternative, NNSA would not construct or operate a BSL-3 facility at LLNL. In this event, NNSA would continue to have its BSL-3-level needs met by exporting work and staff to existing or new BSL-3 laboratories located offsite from LLNL. There would continue to be certain NNSA national security mission needs that could not be met in a timely fashion, or that may not be able to be met at all. The No-Action Alternative would not meet DOE's purpose and need.

Construct and Operate an On-site-Constructed BSL-3 Facility. This alternative would meet NNSA's purpose and need for action. This alternative does not differ significantly from the Proposed Action in terms of operation and decontamination and decommissioning, with one exception. The longer time it would take to construct the facility under this alternative would increase the duration of noise, traffic, and disruption of workers in adjacent buildings. This longer period also means it would be months longer before the facility would be operational.

Remodel/Upgrade a Single-Room Laboratory in Building 365 to BSL-3. Under the Remodel/Upgrade Alternative, NNSA would create a single-room BSL-3 laboratory from an existing BSL-2 laboratory at LLNL. This would require substantial building modification and probable disruption of other ongoing work in the current facility. This alternative would have the lowest waste generation during construction and operation since it would be only a single laboratory while the other two options consist of a facility of three laboratories each. This alternative would meet NNSA's purpose and need for action, but, being only a single BSL-3 laboratory, it would be self-limiting to the amount of research that could be conducted.

ENVIRONMENTAL CONSEQUENCES: The construction and operation of the proposed facility would not pose any significant impacts, either directly or cumulatively when considered in the context of other planned actions, on human health or the environment.

Less than one-quarter acre of previously disturbed land would be used for site preparation, utility installation, and other construction activities. Except for the

temporary disturbance of up to a few feet in depth on parts of the land during site preparation and construction, the effect upon geology, soils, or seismicity would be negligible. Soil erosion-prevention measures (application of the Storm Water Pollution Prevention Plan for mainsite LLNL activities) would be in place during construction. The disturbed construction areas not covered by the building footprint or by parking areas would be reseeded and landscaped to control and minimize erosion from stormwater runoff. No threatened or endangered species habitat are located at or adjacent to the proposed BSL-3 laboratory facility. Due to the previously disturbed nature of the area and the shallow nature of any proposed excavation, there are not expected to be any impacts to potential cultural or paleontological resources. However, if any items of cultural or paleontological significance are uncovered, work would halt until the LLNL archaeologist can assess the find.

Human Health.
Human health effects during construction of the proposed BSL-3 laboratory would be very minor and localized, affecting only workers or officially-sponsored visitors. The proposed action is expected to have no substantial effect on the health of any non-LLNL construction workers. There would be no public human health effects during construction.

The type and rate of injuries and illnesses expected during operation of the proposed BSL-3 laboratory would be the same as those demonstrated for CDC-registered laboratories, U.S. Army Biological Defense Research Program (BDRP) laboratories, and existing biological research laboratories operated by LLNL. There has been an extremely low incidence of laboratory-acquired infections associated with operations in CDC-registered laboratories since the implementation of CDC-developed guidelines issued in 1974. Experience with biological research laboratories at LLNL spans a period of many years. LLNL has operated BSL-1- and BSL-2-equivalent laboratories for at least the last 20 years without any infections associated with their operation. Also, there were no unintentional releases to the environment or to the public associated with the LLNL biological research laboratories. Based on extensive experience with the safe handling of biological materials at LLNL and the Department of the Army, it is projected that the National Defense-related and scientific research to be conducted at the proposed BSL-3 facility would not result in a significant impact from normal operations to the workers or the public. The combination of utilizing the guidelines, standards, practices, and procedures established by the CDC, NIH, Human Health Services, and Public Health Services, together with BSL-3 safety equipment and facility safety barriers, results in an overall potential risk of illness to site workers or visitors from operations involving infectious agents that would be best characterized as minor. Also, a substantial release of infectious microorganisms from the confinement of the facility (specifically at greater than infectious dose quantities) would be unlikely to occur under those operating parameters. The maximum potential impact per liter of air at 125 ft (38 m) from the building exhaust that could derive from the bounding accident that might occur from handling infectious material is projected to be less than one one-hundredth of the dose that would be infectious to an individual 50% of the time (HID_{50}). The nearest site boundary to the general public would actually be approximately one-half mile away,

further reducing the potential for even a tiny fraction of one individual HID_{50} reaching the site boundary. There would be no discernible public human health effect from BSL-3 laboratory operations at the proposed facility.

Potential Pathways for Infectious Agents to Escape BSL-3 Containment. Potential means for infectious agents to leave the BSL-3 containment and possibly cause human health impacts would include five pathways:

Direct Transmission. Direct transmission would first require a worker to be exposed to an infectious agent. The likelihood of a worker inhaling or otherwise becoming exposed (for example, through cuts in the skin or ingestion) to an infectious agent would be extremely remote. Operations as described minimize opportunities for direct transmission. This potential is further reduced through the intervention of effective vaccines or therapeutic measures.

Vector-borne Transmission. The facility would be designed to severely limit the potential for possible vector-borne transmission through insects and rodents. The use of pest control programs would limit the potential for transmission of infectious agents from animals to humans.

Vehicle-borne Transmission. The primary concern for vehicle-borne transmission would be by the workers' clothing or skin and hair, as all other materials leaving the BSL-3 must go through sterilization by autoclave or chemically. The guidelines (established by the CDC and NIH) to be followed within the proposed BSL-3 facility would minimize this potential for a worker to unknowingly transport infectious microbes from the facility.

Airborne Transmission. Air leaving the BSL-3 laboratories during operating conditions would be doubly HEPA-filtered prior to emission through stacks on the building roof. HEPA filters at the LLNL BSL-3 facility (including those in the biosafety cabinets [BSC]) would be tested annually and replaced as necessary. Given the proposed operations of the facility, there is no expectation that the HEPA filters would become moisture-saturated or torn (the two major reasons for HEPA filter failures). The number of viable vegetative microorganisms after HEPA filtration would be near zero. Also, regardless of the presence or failure of HEPA filters, many environmental factors (including ultraviolet light, dehydration, high temperatures, freezing temperatures, and the presence of free oxygen) present would effectively and naturally kill airborne microbes in their vegetative state.

Water-borne Transmission. Potable water would not be affected by the implementation of the Proposed Action. Facility design features, such as backflow-preventers and State-of-California-adopted uniform plumbing code requirements, would prevent microbes within the facility from migrating back through the water supply piping to the public. Water exiting through the sink drains would be diverted to a retention tank where it would be disinfected before being sent to the sewer system and the LWRP facility.

Rodent Handling Operations. The proposed facility would use a state-of-the-art ventilated caging system designed for easy cleaning, with high rates of exchange air, and HEPA-exhausted for worker protection and for research quality maintenance. Also, once exposed to a pathogen or toxin, the rodents would not leave the cages except inside a BSC. An inadvertent needlestick (autoinjection) or rodent bites and scratches can be

averted by adhering to standard operating procedures (SOPs) and safety procedures using safety equipment that virtually eliminate these occurrences. When handling human pathogens or zoonotic disease-causing agents (capable of being exchanged between humans and other animals), workers would use personal protective equipment (PPE) and would be either immunized and/or would have medical treatment available (prophylaxis) for the specific pathogen being handled. Human pathogens for which there is no immunization or prophylaxis would not be handled in the proposed BSL-3 laboratory, in accordance with the CDC/NIH guidelines.

Rodent Challenge Studies. Aerosol studies using rodents such as mice and rats to be planned for the proposed activity would only be done inside a biosafety cabinet (BSC) that meets all currently applicable CDC/NIH requirements for the materials involved. The small aerosol-challenge device (collision nebulizer) would have its reservoir filled while in the BSC. The rodent challenged with the aerosol would be placed into a clean cage. The nebulizer would be cleaned and chemically disinfected while still in the BSC. Compressed air would be immediately disconnected at the end of the process of challenging the rodent. After removal from the BSC, the device and all its parts also would be put into an autoclave to insure sterilization.

Biotoxin Research. The proposed facility would have appropriate procedures in place prior to operation of the facility. The probability of being exposed to a biotoxin would be extremely low when appropriate safeguards and other safety procedures are followed. The nearest member of the public would be about one-half mile away and would have a very low likelihood of being exposed to even a small dose of biotoxins. Adverse health effects to uninvolved workers in adjacent buildings or visitors would be extremely unlikely to develop from this activity. Any adverse effect to the environment from the accidental release of non-indigenous organisms would be extremely unlikely as well.

Transportation. The addition of milliliter-quantity samples being shipped to and from the BSL-3 facility through the U.S. Postal Service or by commercial or private courier would not be expected to change the overall risk of transportation accidents. Samples could consist of cells in media contained within DOT-certified packages. The consequences of such accidents would be anticipated to be minor, based on the historical data.

Chemicals/Materials Use.
The proposed laboratory would not use radioactive materials, propellants, or high explosive materials, and the quantities of hazardous chemicals stored in the facility at any one time would be just a few liters each of chemical disinfectants (such as sodium hypochlorite or potassium hypochlorite) and biologic stabilizers (phenol). Chemicals such as paraformaldehyde would not be stored in the facility but would be brought in only when required for room fumigation. The chemicals used and stored would be tracked using ChemTrack (LLNL's computerized chemical inventory system) and would be handled in accordance with LLNL directives and guidelines for environment, safety, and health.

Noise.
Members of the public would not be exposed during construction to noise levels exceeding City of Livermore planning and zoning code standards (ambient noise level greater than 75 dBA beyond the boundaries of the site, nor greater than 60 dBA at the boundary of a residential district), predicated on the distance of the proposed facility being about one-half mile to the nearest residence.

Air Quality.
The proposed action would not lead to an adverse impact on air quality. Dust suppression measures would be implemented during site preparation and construction, as necessary, to minimize any temporary increase in particulate emissions. Since very few pieces of heavy equipment generating combustive-engine exhausts would be used, and for limited time, their potential effect on ambient air quality would be temporary and localized. No additional emergency generators, boilers, or other fuel-burning equipment would be added as a consequence of building and operating the proposed BSL-3 facility. Periodic use of disinfecting gases could be part of the routine operation of the facility. These gases or vapors, such as formaldehyde (from paraformaldehyde) would not affect the local air quality since they would be inactivated at the end of each use. Effects of these gases, if any, would be temporary and localized and would dissipate very quickly. HEPA filtration of all laboratory exhausts removes virtually all biological particles and, therefore, there would be no incremental increase of air contaminants due to BSL-3 laboratory operation.

Waste.
The incremental increase in waste materials produced during site preparation and construction (construction debris and excess uncontaminated soil from excavation activities) would be minimal with respect to the waste production of the entire LLNL facility. The incremental sanitary sewer waste production associated with the operation of the proposed facility would be minimal when compared to the total waste volumes generated by the entire LLNL facility and negligible with respect to the City of Livermore's sewer system discharge. Although no discharge limits currently exist for infectious materials which are commonly discharged by BSL-3-level healthcare and veterinary facilities and laboratories or homes, liquid waste as generated from the proposed BSL-3 laboratory operations would be discharged first to a retention tank system (for containment, characterization, and further disinfection as needed) prior to discharge to the sanitary sewer system. Minimal amounts of hazardous waste (less than 2 gallons per year) would be generated by the facility. Most hazardous chemicals would be used up in process or leave the building as a stabilizing product for microorganisms and biological material.

Other impacts.
The proposed action would include very minimum hiring and, therefore, would not result in an increase in demand for local housing, when considered cumulatively with other DOE actions that could increase employment. In addition, the increase in employees would not contribute to any additional traffic congestion at the LLNL site or in the local

area. No adverse impact is expected to any minority or low-income populations and, therefore, no environmental justice issues are associated with this project.

Terrorism
NNSA has reviewed the threat to the facility from terrorists and the potential environmental effects that might derive from various terrorist acts against the facility. Three terrorist acts were considered: 1) a terrorist attack resulting in facility damage; 2) a theft of pathogenic agent by a terrorist from outside of LLNL; 3) a theft of pathogenic agent by an insider. This review finds that:

1. a successful terrorist attack involving facility damage and loss of containment is not expected to occur due to the extensive layered security programs at the LLNL; in any event, the environmental consequences would be bounded by the effects that would occur during catastrophic events or operational accidents;
2. because pathogenic agents are available in nature and other, less secure locations, operation of the LLNL BSL-3 facility would not make pathogenic agents more readily available to an outside terrorist, or increase the likelihood of an attack by an outside terrorist; and
3. the theft of pathogenic materials by an insider from any bio research facility could have very serious consequences; this scenario is not expected to occur at LLNL due to human reliability programs, security procedures, and management controls at the BSL-3 facility.

NNSA believes that the probability of a successful terrorist attack on the BSL-3 facility is so uncertain that the possibility of such an event cannot be accurately quantified. The systems and technologies developed in the proposed facility would likely reduce the probability and consequence of a bio-terrorist act against the public in general.

PUBLIC COMMENTS ON THE REVISED EA: The EA was circulated for review and comment to the State of California and other interested stakeholders for a 30-day comment period that ended on June 11, 2007. Appendix C of the EA contains the DOE/NNSA responses to specific comments received during that public comment period.

DETERMINATION: Based on the analysis in the EA, and after consideration of all comments received, DOE/NNSA has determined that the proposed action does not constitute a major federal action significantly affecting the quality of the human environment within the meaning of the *National Environmental Policy Act of 1969*, 42 U.S.C. 4321 et seq. Therefore, preparation of an Environmental Impact Statement is not required and DOE/NNSA is issuing this notice of Finding of No Significant Impact (FONSI).

PUBLIC AVAILABILITY: Copies of this EA (DOE/EA-1442R) and FONSI are available from:

Samuel Brinker
Document Manager
Livermore Site Office
U.S. Department of Energy
P.O. Box 808, L-293
Livermore, CA 94550
Phone: (925) 422-0710

For further information regarding the NEPA process, contact:

Karin King
NEPA Compliance Officer
Livermore Site Office
U.S. Department of Energy
P.O. Box 808, L-293
Livermore, CA 94550
Phone: (925) 422-0756

Issued this 25 day of January, 2008.

Camille Yuan-Soo Hoo, Manager
Livermore Site Office

EXHIBIT 5

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

JOSEPH P. RUSSONIELLO
United States Attorney
CHARLES O'CONNOR
Assistant United States Attorney
450 Golden Gate Ave., Box 36055
San Francisco, CA 94102
Telephone: (415) 536-6967
Facsimile: (415) 436-6748

RONALD J. TENPAS
Assistant Attorney General
BARCLAY T. SAMFORD (NMBN 12323)
Trial Attorney
U.S. Department of Justice
Environment & Natural Resources Div.
1961 Stout St., 8th Floor
Denver, CO 80294
Telephone: (303) 844-1475
Facsimile: (303) 844-1350

Attorneys for Defendants

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

TRI-VALLEY CARES, MARYLIA KELLEY, JANIS KATE TURNER, and JEDIDJAH DE VRIES Plaintiffs, v. UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION, LAWRENCE LIVERMORE NATIONAL LABORATORY, Defendants.	Case No. 08-cv-1372-SBA DECLARATION OF ERIC GARD

I, Eric Gard, hereby declare and state as follows:

1. I am the Program Leader for Biological Surveillance and Detection at Lawrence Livermore National Laboratory (LLNL). I have held this position for several years and have the responsibility for overseeing research, development, testing and evaluations for biological detection projects here at LLNL. I have a Ph.D. in Chemistry and 15 years of experience as both a researcher and program manager working at the interface of biology and chemistry. In the past 10 years I have been working heavily in the area of biological threat detection and have experience working with and managing select agent activities. I have published numerous peer reviewed articles on biological detection.

2. The purpose of this declaration is to describe the importance of continuing operations at the LLNL Bio-safety Level 3 (BSL-3) facility, and some of the adverse impacts to LLNL and to national security if operations at the facility were halted by an injunction.

3. The LLNL BSL-3 facility became fully operational January 25, 2008 with BSL-3 level containment with respect to laboratory practices/techniques, safety equipment, and facility design. Our current inventory of organisms in the BSL-3 facility is less than 15 ml. We plan to continue to expand our collection of organisms and perform organism growth and DNA/RNA isolation experiments over the next few months.

4. In order to facilitate an orderly disposition of Plaintiffs' Motion for a Preliminary Injunction we have voluntarily agreed, until May 9, 2008, to the following limitations on operations:

a. No aerosol testing;

b. No rodent infection experiments;

c. No production, generation, or knowing receipt of genetically modified biological material that would require management of the facility at the BSL-3 level; and

d. The total amount of biological agents in the facility for which BSL-3 containment is recommended in the 4th Edition of *Biosafety in Microbiological and Biomedical Laboratories* shall not exceed 100 milliliters (ml).

4. While the LLNL BSL-3 facility is authorized to hold a maximum volume of approximately 50 liters of bioagent (composed of separate 2 ml cryo-vials) the inventory will increase slowly over a period of years and it is unlikely that it will ever reach this maximum inventory level. It is also important to note that during normal operation, there will only be a few (approximately one to five vials) 2 ml cryo-vials that have been thawed for use in an experiment. This means that during operations, the remainder of the inventory will be secured in locked -80 degree Celcius freezers.

4. A preliminary injunction halting operations at the LLNL BSL-3 facility will have significant negative ramifications on LLNL's Biological Security Program. For example, LLNL is currently in the midst of the annual funding proposal cycle for DHS and other federal agencies. If the BSL-3 operations are halted for even 60-90 days, our researchers will not be able to request funding for BSL-3 activities at LLNL during this annual call for proposals. Because this funding cycle occurs only once a year, even a short injunction

could translate in the loss of funding for an entire year. The immediate impact of an injunction will translate into the loss of jobs for up to eight staff currently trained to operate in the BSL-3. It is also my opinion that it is unlikely that the facility will ever regain operational status with the loss of funding support and corresponding loss of work for an entire year. This would result in even more significant job losses in the next 6-12 months. The impact of loss of future business could include an additional eight staff that were planned to complete training to utilize the BSL-3 in their research.

5. Any interruption in operating the BSL-3 facility at LLNL will also have a profoundly negative impact on long-term staff retention and recruiting. For LLNL to fulfill its bio-defense role for the country it is critical that we have the infrastructure to fulfill our mission. The lack of an operational BSL-3 facility deprives our staff working in the field of the basic tools they need to conduct relevant research. Without these basic tools researchers will not be able to sustain their careers in this area at LLNL, and it will be difficult to retain current staff and to attract new staff to LLNL to work in this nationally important research area. Total staff working in bio-defense research is approximately 120 with 8 currently doing research in the BSL-3, and 8 additional staff awaiting training to allow access to the research laboratories. These 16 BSL-3 trained staff provide critical experimental data required by the full 120 bio-defense researchers to ensure program deliverables are met. The affect is that the lab researchers support the larger research business volume for bio-defense projects.

6. I am familiar with the Plaintiffs' allegation that the increase in the number of BSL-

3 facilities nation-wide means there is no longer a need for the facility at LLNL. The continued need for the BSL-3 at LLNL is driven primarily by the Department of Homeland Security's (DHS) Biowatch program, a national biological detection and response network designed to protect the country from biological attack The success of the Biowatch program depends in part on efficient sample processing, the ability to handle a variety of organisms concurrently, and the assurance of sample security and integrity during the various stages of analysis (i.e. chain of custody). LLNL plays a vital role in the continued operation of this detection network by running several Biowatch analysis laboratories and providing next generation detection assays and instrumentation. Should a biological attack occur, LLNL is one of only a few key laboratories where the confirmation testing and bioforensics can take place; most of which would require the BSL-3 laboratory. It is the uniqueness of how the LLNL BSL-3 facility contributes to this national biodefense response network that separates it from the other BSL-3 labs that have opened between issuance of the draft and final Revised EAs. In addition, as part of this response network, LLNL will have confirmatory assays, approved sample handling methods, and authorization to work with multiple agents of concern to DHS. This is not the case for most BSL-3 laboratories in the country.

7. The BSL-3 facility at LLNL is located in the center of a highly secure one square mile research facility. Four separate and distinct layers of physical security access are required for those working in the BSL-3 facility. In conjunction with the physical security, workers in the facility are also required to possess a DOJ clearance, undergo physiological evaluation, random drug testing, and pass a large number of BSL-3 specific training

classes. In my 15 years of experience with biological research, these security requirements, when taken together, are significantly higher than those in place at most of the country's BSL-3 facilities.

8. For these reasons, it is my professional opinion that LLNL's BSL-3 facility is extremely safe, secure, and will significantly improve our Nation's ability to detect and respond to the threat of terrorism using biological agents, and that halting operations at LLNL's BSL-3 facility would directly and adversely impact the national security of the United States.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief. This declaration was executed in Livermore, California, on March 25, 2008.

Eric Gard

EXHIBIT 6

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

APPENDIX C: **Public Comments on the EA**

C.1 Response to Public Comment Letters/Email Messages

In response to a September 16, 2003 lawsuit filed in Federal District Court challenging the adequacy of the 2002 EA, the Court ruled that the EA was adequate. In response to an October 2006 appeal by the Plaintiffs, the Ninth Circuit concluded that while DOE did take a hard look at identified environmental concerns and that its decision was fully informed and well-considered, the DOE did not consider whether the threat of potential terrorist activity necessitates the preparation of an environmental impact statement and thus remanded the matter to the DOE. In response to this ruling and new DOE guidance, DOE has revised the 2002 EA to consider the potential impacts of terrorist activity. The revised Draft Environmental Assessment (EA) was made available for public comment from May 11, 2007 to June 11, 2007. Over 80 comment responses were received from residents of 8 different states and the District of Columbia.

For this document, the public comment appendix from the 2002 EA has been supplemented to include a summary of additional public comments that provided new information pertinent to the proposed action or expressed concerns that were not previously responded to in the original document. Letters and emails providing comments on the Revised EA are included in Section C.2.

1. NEPA Compliance: Documentation/Review Level.

Several commenters expressed the opinion that a BSL-3 facility at LLNL would allow for experiments with a broad spectrum of biotoxins and biological materials/agents. They believed that this would be a new program for DOE and LLNL that, if inadequately analyzed before proceeding, could endanger the workers and the community. Commenters indicated that the draft EA provided only boilerplate assertions that the risks would be negligible, and relies on adherence to procedures, some of which DOE laboratories have not followed in the past according to the commenters. Consequently, they believe that a further environmental review in the form of a project-specific Environmental Impact Statement (EIS) should be conducted. Some of the same commenters were of the opinion that the proposed project represents an integrated new program area for the DOE, and as such, a Programmatic EIS (PEIS) should be prepared to review the effects of undertaking work in this "new" mission area. Several commenters expressed the opinion that the purpose and need for the proposed action at LLNL is without precedent, and the commenters called for a complete NEPA review (PEIS) of the NNSA Chemical and Biological National Security Program (CBNP) which some referred to as the "Chemical and Biological Nonproliferation Program."

One commenter expressed the opinion that "... analysis of terrorist risk at a BSL-3 facility is far too significant to be performed using an interim guidance, which does not include the full requirements and which may be changed in the final guidance. DOE/NNSA must withdraw this revised EA and release a second revision of the EA for public review following the finalized guidance."

Several commenters noted that NNSA withdrew the EA for the BSL-3 facility at the Los Alamos National Laboratory (LANL) and is currently preparing an Environmental Impact Statement. Commenters suggested that since NNSA is preparing an EIS for the LANL BSL-3, NNSA should prepare an EIS for the LLNL BSL-3.

Response

LLNL has been a national focus of bioscience research for almost four decades. Bioscience researchers at LLNL already safely conduct research at BSL-1 and BSL-2 levels in disease susceptibility, prevention, diagnosis, treatment, and rehabilitation and in support of National Institutes of Health (NIH), DOE, and NNSA mission requirements, LLNL already works on research aimed at detection and identification of biological warfare agents. The Biology and Biotechnology Research Program (BBRP) at LLNL also contributes to a number of high-profile national-level efforts in both health-related bioscience research and in developing defenses against the potential use of biological-warfare agents against either our civilian population or military forces. This work involves close cooperation with other national laboratories, DOE, and other agencies (e.g., health, military, and law enforcement). Currently, research conducted at the existing LLNL BSL-2 laboratories involves anthrax (Bacillus anthracis) and plague (Yersinia pestis). This research includes supporting development of tests for quick identification of plague based on a DNA signature and the development of decontamination reagents. Operation of a BSL-3 facility would not constitute a new or unique role for LLNL, would not be inconsistent with existing DOE mission work, and would not be unique or without precedent.

The EA analysis considered effects relating to human health, ecological resources, air quality, noise, waste management, soils, geology, and seismology. Effects to these resource areas were minor in nature. Human health effects are expected to be no different from those at other U.S. Centers for Disease Control and Prevention (CDC)-registered laboratories operated according to CDC and NIH guidelines. Those laboratories experience very infrequent worker accidents with minor or no consequences to workers and members of the public. Socioeconomics, visual resources, transportation, utilities and infrastructure, cultural resources, environmental justice, and environmental restoration resources were identified as being unaffected by the construction and operation of the BSL-3 facility; or as being minimally affected and inherently mitigated by the project design; or as being minimally affected and temporary and intermittent in nature. Because the potential effects of the project are not significant in terms of context and intensity, the NNSA has concluded that the potential project effects do not require preparation of a project-specific EIS.

When considering the issue of preparing a programmatic NEPA analysis, a Federal agency must determine whether the program in question meets the Council on Environmental Quality (CEQ's) NEPA Implementing Regulations (40 CFR 1508.18(b)(3)) definition of a major federal action, which includes the: "Adoption of programs, such as a group of concerted actions to implement a specific policy or plan; systematic and connected agency decisions allocating agency resources to implement a specific statutory program or executive directive." These regulations also address when an agency must prepare a programmatic analysis, including the analysis of cumulative effects. A programmatic analysis is necessary where the proposals for federal action "are related to each other closely enough to be, in effect, a single course of

action." Additionally, the CEQ regulations speak to the scope of NEPA EISs (40 CFR 1508.25(a)(1)) and to connected actions such as those that "automatically trigger other actions which may require EISs"; "cannot or will not proceed unless other actions are taken previously or simultaneously"; or "are interdependent parts of a larger action and depend on the larger action for their jurisdiction". DOE and NNSA conduct biological research at various facilities across the DOE complex of national security laboratories and other research institutions. This research began in the late 1940s when the DOE's predecessor agency recognized the need for obtaining information about the effects of radiation on humans and other biota. As an outgrowth of this research, many individual studies and research projects have been conducted over the years both for the benefit of DOE (and its predecessor agencies) and as "work-for-others" projects with sponsors from the private sector and other Federal agencies. Each of DOE's facilities has developed specialized areas of focus and expertise and on some occasions have contributed their expertise to performing portions of work that has been pulled together to answer complex questions or reach complex goals, such as work performed recently to map the human genome. At this time, the NNSA believes that these research efforts consist of projects too diverse and discrete to constitute either a "major Federal action" or activities sufficiently "systematic and connected" so as to require a programmatic NEPA analysis, especially an EIS. Not only are the research projects diverse, they are discrete and independent in nature. They are separately operated and approval of one project does not insure the approval of other similar projects. Success in one project area does not invariably affect the variety or direction of NNSA's research, in as much as NNSA's research program is largely reactive, designed to respond to the needs of NNSA, DOE, and other user groups and consumers. While DOE responded to the 1996 Congressional passage of the Defense Against Weapons of Mass Destruction Act, which authorized the DOE to establish a Chemical and Biological Weapons Nonproliferation Program (now known as the Chemical and Biological National Security Program), its research has continued to build upon existing research expertise present at its various research institutes. DOE and NNSA have not expanded their research such that their projects are concerted or systematic and connected. Mere commonality of objectives is insufficient under the CEQ's NEPA Implementing Regulations to constitute a "major Federal action" requiring NEPA compliance in the form of a programmatic NEPA analysis. While NNSA's biological research projects all pertain to biota and are ultimately directed toward the support of NNSA's national security mission, these rudimentary similarities are not sufficient to bind the universe of research projects conducted by DOE and NNSA into a "program" as this is identified by the CEQ's NEPA Implementing Regulations (40 CFR 1508.18(b)(3)). NNSA is therefore of the opinion that no programmatic NEPA analysis is necessary at this time for biological research conducted at its facilities and this EA is sufficient to meet NNSA's NEPA compliance requirements with regard to the construction and operation of the proposed BSL-3 facility at LLNL.

On December 1, 2006, the DOE Office of NEPA Policy and Compliance issued a memorandum on the subject "Need to Consider Intentional Destructive Acts in NEPA Documents". This document provided guidance on the need to analyze intentional destructive acts in NEPA documents. The document states "While ... further guidance is in preparation, DOE NEPA practitioners should immediately implement the guidance in this notice to explicitly consider the potential impacts of intentional destructive acts in NEPA documents... ". It is therefore

appropriate and consistent with the intent of the memorandum to develop this EA using the guidance provided by that document.

The "Notice of Intent To Prepare an Environmental Impact Statement for the Operation of a Biosafety Level 3 Facility at Los Alamos National Laboratory" from the Federal Register (Vol. 70, No. 228, November 29, 2005) explains NNSAs basis for determining that an EIS should be prepared for the LANL facility. In 2002, prior to constructing the facility, NNSA analyzed the project pursuant to NEPA and determined that an EA appropriate level of review. An EA was prepared and a Finding of No Significant Impact (FONSI) for the construction and operation of the facility was issued. After completion of the NEPA process and facility construction, NNSA identified new information concerning the BSL–3 Facility. NNSA determined that it was necessary to conduct additional seismic analysis of the location of the building on fill material on the sloping side of a canyon. Therefore, in early 2004, NNSA withdrew the portion of the FONSI that dealt with the operation of the BSL–3 Facility, and announced that it would prepare a supplemental EA on its proposal to operate the facility. In January 2005, NNSA published a Notice of Intent to prepare a Supplemental Site-wide Environmental Impact Statement (S–SWEIS) for the continued operation of LANL. The notice stated that if a FONSI for operation of the BSL–3 Facility could not be issued, the analyses of the potential impacts of operating this facility would be included in the S– SWEIS. NNSA then decided to prepare a new Site-wide EIS for LANL (SWEIS) rather than to supplement the 1999 SWEIS instead of a S-SWEIS. The Federal government, and in particular the intelligence community, was concerned that any delays in the schedule for the SWEIS could further delay a decision on whether to operate this critical homeland security facility. Because of these events, NNSA decided that preparation of an EIS was appropriate for operation of the LANL BSL–3 Facility and that this analysis should be conducted separately from the new SWEIS. This decision is not pertinent to the NNSA determination that an EA is the appropriate level of NEPA documentation for the LLNL BSL-3 Facility.

2. Safety of Laboratory Operations

Several commenters expressed the general opinion that LLNL has a history of leaks, spills, fires, explosions and accidents. They indicated that this information concerning operational history is relevant but is not included in the draft EA on DOE's response to build and operate a BSL-3 facility. Commenters also stated that the CDC is more qualified than LLNL and they should be handling the BSL-3 research. Commenters expressed the opinion that issues of safety of lab operations are especially important in light of the February 2001 DOE Office of Inspector General (IG) report entitled "Inspection of Department of Energy Activities Involving Biological Select Agents." Some commenters also felt that it is "a huge leap between BSL-2 and 3 facilities" and that "safety measures and procedures... are vastly different, as are the risks." Another commenter stated in reference to the IBC that "there is no indication whether there will be a process to guarantee full public scrutiny of committee deliberations."

Comments on the Revised Draft EA did not express any new concerns or provide information that was new and pertinent to the safety of laboratory operations. However, DOE received additional comments after the public comment period regarding the laboratory-acquired

infections. In response, additional information discussing laboratory-acquired infections since 2002 was provided in Section 4.2.2.2 "Analysis of Abnormal Events and Accidents for Facility Operation".

Response

Since it was founded in 1952, LLNL has been managed by the University of California. While mistakes, accidents, leaks, and spills will inevitably occur, LLNL is committed to providing employees and the community with a safe and healthy environment. LLNL has had an infrequent history of incidents and none has resulted in a significant impact to the public or the environment. In 2000, DOE's Integrated Safety Management System (ISMS) was implemented at LLNL, resulting in better safety practices and greater safety awareness. A DOE Verification Team inspected safety procedures at 25 facilities across the Laboratory, reviewed over 700 supporting documents, and determined that LLNL effectively implemented ISMS. The response to comment 11 (Waste Disposal) below discusses LLNL's compliance with permit limits for discharges into the sanitary sewer (between 99 and 100 percent compliance from 1996 to 2000) and LLNL's record of inspections for compliance with the California Medical Waste Management Act. As discussed in Section 4.1.2 of the Draft EA, LLNL has operated BSL-1- and BSL-2-equivalent laboratories for the last 20 years without any infections associated with their operations and no unintentional releases to the environment or to the public.

The CDC, which is part of the Department of Health and Human Services, provides guidelines for the operation of BSL-3 facilities, registers facilities that will access, use and transfer select agents, and then periodically inspects these facilities during operation. The CDC through the Antiterrorism and Effective Death Penalty Act of 1966 (See Appendix A-2) controls the transfer and receipt of select agents. As described in Appendix A-1, each successive CDC-defined biosafety level builds upon the previous level practices, safety equipment (primary barriers), and facility requirements (secondary barriers). These practices go, for example, from limited access to controlled access, decontamination of only "needed waste" to all waste, and defining medical surveillance requirements to requiring specific baseline serum. Safety equipment requirements for BSL-2 and BSL-3 laboratories are the same, except that in a BSL-2 facility the biosafety cabinets (BSC) are required only for manipulations of agents that cause splashes or aerosols of infectious materials. In a BSL-3 facility all open manipulations are conducted in a BSC. BSL-3 laboratories within facilities need physical separation of areas, self-closing double-door access, and controls on ventilation systems that do not permit air recirculation and have negative airflow into BSL-3 laboratories. BSL-2 laboratories do not have these requirements. Therefore, the engineering controls built into a BSL-3 facility are significant, but there is not a huge technological difference between a BSL-2 facility and a BSL-3 facility. LLNL institutionally uses the same types of facility controls in its other facilities.

CDC laboratories perform work that is different from the research work performed at LLNL. The CDC contracts with DOE and NNSA facilities, as well as with other government and private facilities (due to their capabilities), to perform much of its needed research work, rather than duplicating the research expertise of these agencies within the Department of Health and Human Services. While it is the opinion of some commenters that only the CDC should perform this work, this is neither cost effective nor practical. (Safety measures are discussed further under the response to comment topic 5).

The IG report cited by the commenters (DOE/IG-0492 dated February 2001) states at the beginning of the Observations and Conclusions Section: "We found no evidence that the Department's current biological select agent activities have adversely impacted the safety and health of DOE and contractor employees or the public". The IG observed that the Department had not developed and implemented policies and procedures that establish clear roles and responsibilities for the conduct of activities involving biological select agents and select agent materials. Additionally, the IG stated their opinion that the Department had not ensured that DOE laboratories, including those managed by the NNSA, follow "best practices" for the operation of these facilities. The concluding section of the IG Report, "Inspector Comments", contains the statement: "We believe the corrective actions identified by the Department are responsive to our recommendations." By the date of issuance of the IG report in February 2001, the DOE had already corrected identified problems associated with its management of facilities at which biological select agent work is conducted. At the time of the IG inspection, LLNL had already incorporated the provisions of the CDC/NIH Guidelines into its work standards for operation of its BSL-2-level facilities and was compliant with its provisions. The IG report had no adverse findings with regard to LLNL activities involving operation with biological select agents. DOEs operating contract with the University of California (UC) also requires that LLNL implement the CDC/NIH Guidelines through their Work Smart Standards and their ES&H Manual.

The currently established Institutional Biosafety Committee (IBC) will have authority over approving projects conducted at the proposed BSL-3 facility at LLNL, as it does for current BSL-1 and BSL-2 operations at LLNL. (The role of the IBC is discussed further under the response to comment topic 4 below.) NNSA will maintain strict adherence to the CDC and NIH guidelines for operating a facility of this nature. DOE oversight actions would also continue to be responsive to the recommendations made by the IG report.

(Additional responses related to safety are discussed under comment topic 5 and security measures are addressed in comment topic 7 below.)

3. Defensive- vs. Offensive-oriented Research

Several commenters expressed their concerns about siting a BSL-3 facility at a nuclear weapons design lab. The commenters questioned how the DOE would prove that this new work with bio-agents is defensive and would not be used in the future for the manufacture of biological weaponry. The commenters expressed their opinions that the proposed culture of some organisms (*Brucella spp., Coccidiodes immitis*) suggests the potential development of agents that could aid U.S. offensive military operations. Commenters also expressed concerns about collocating a BSL-3 facility close to the existing LLNL Environmental Microbial Biotechnology Facility (EMBF), suggesting that it implied existence of future operation of an offensive biological weapons program at LLNL. The commenters were of the opinion that, since the EMBF is a biological fermentor with a capacity in excess of 1500 liters, the facility could be used for industrial-scale production of biological select agents with weapons applications. Commenters cited the proposed production of up to one liter of biological agent at the BSL-3

facility as excessive for defensive research purposes, suggesting that gram or sub-gram quantities of any agent are sufficient for such research. The proposed rodent aerosol challenge tests prompted commenters to infer that this would necessitate weaponization of agents and could pose increased dangers to workers and the public. It was the commenters' opinion that the Draft EA failed to address the risks posed by the aerosolizing, or as the commenter alleges: "weaponization." Another commenter stated that the proposed facility is not a small facility based upon CDC definitions (42CFR72.6(j)). One commenter expressed the opinion that, in addition to a Programmatic NEPA review of DOE's biological warfare defense research, a Nonproliferation Impact review should be conducted.

Commenters expressed similar concerns about the Revised Draft EA. Several commenters noted that other NNSA documentation describing the BSL-3 Facility list storage capacities of up to 25,000 2 ml vials and expressed a concern that the total capacity of the facility is therefore 100 liters of biological material.

In other commenter's opinions, the Revised Draft EA should include a Nonproliferation Impact Review that includes public participation because "This open process is critical because intent really is the biggest differentiating factor between defensive and offensive biological research."

Response

NNSA acknowledges that many people are opposed to the research, development, and testing of nuclear weapons, weapons research, and testing using live microorganisms. However, Congress directs DOE and NNSA with regards to the missions, and work performed at their facilities must support congressionally mandated missions. Similarly, the Department of Defense (DoD) must respond to its Congressionally assigned missions. Departmental mission support activities have necessitated biological research projects in the past, and this requirement will likely continue into the future for elements of both departments. As discussed in the response to comment topic 1 above, defensive biological research is ongoing at LLNL, is performed in support of DOE and NNSA mission requirements, and would not be inconsistent with existing DOE mission work.

NNSA also acknowledges that certain individuals might see the proposed BSL-3 facility as adding to the perception that the U.S. plans to prepare bioweapons for development of an offensive capability. However, the U.S. is a signatory to the Biological and Toxins Weapons Convention Treaty and has agreed that this nation shall not perform the actual development and production of bioweapons. Additionally, all such U.S. offensive capabilities were destroyed and offensive-oriented research was halted after the 1969 Presidential decision. Nonetheless, if the U.S. were indeed now planning a major departure in its 33-year-old policy on offensive capabilities, such work would require a facility with different functional capability and of a larger size than the proposed three-laboratory room BSL-3 facility. The microbiological research sample preparation equipment being proposed for the LLNL BSL-3 laboratory would not be the correct type needed to support a bioweapons production facility. Unlike the proposed BSL-3 facility at LLNL, a bioweapons production laboratory would require much more floor space to accommodate a sizeable worker staff and multiple pieces of specialized equipment. DOE does not now, and does not propose to, conduct research or engage in preparation or production of biological materials or toxins for potentially offensive use or purposes at LLNL and it would not be allowed under the Biological Weapons Convention.

It is true that a number of organisms that could potentially be used in research at the proposed BSL-3 facility, including the organisms mentioned by the commenter, could have offensive uses. But research currently being conducted by LLNL and proposed research in a BSL-3 facility would be for defensive purposes. For example, work conducted at LLNL by the Biology and Biotechnology Research Program (BBRP) in 2001 was focused on two areas: advanced detection systems to provide early warning of an attack; to identify the populations at risk, contaminated areas, and facilitate prompt treatment; and to develop DNA signatures and biological forensics technologies to identify the agent, its geographical origin, and/or the initial source of infection. Work in the proposed BSL-3 facility is limited to quantities less than 10 liters (working with over10 liters of culture quantities defines the NIH threshold for a "large-scale research or production" facility). The proposed BSL-3 facility and its operation would be limited to less than 1 liter of cultured microorganisms as the maximum quantity handled in any BSL-3 laboratory room at any point in time. Some research that the proposed facility would conduct requires growth media of up to "liter-size" quantities in order to have sufficient material from which to extract enough genetic material to conduct certain types of genetic research such as that involving messenger RNA. Additionally, organisms such as Coccidiodes immitis, already being investigated by LLNL, are locally important (Valley fever or San Joaquin fever) and research on this is public health related and extremely important to California and the nation at large. DOE believes that work conducted in the facility will not lead to proliferation of offensive biological weapons capabilities and that the EA makes it clear that the proposed facility is not designed as a production facility for offensive research or weapons production. With regard to the additional need for a "Nonproliferation Impact Review" the NNSA is of the opinion that none is required. While NNSA will ensure that the proposed facility would comply with the BWC there is no formal process requiring a "Nonproliferation Impact Review" per se and therefore none would be implemented by the NNSA.

There is no affiliation between the EMBF's 1500-liter fermentor and the proposed BSL-3 facility. The EMBF was established for the investigation, development, and growth of microorganisms that have environmental remediation applications. The facility can also be used for other biotechnological studies, such as the production of microbial pharmaceuticals and food additives. However, the facility is not suited for activities involving pathogenic organisms. BSL-3 facility protocols and engineering and design requirements in conformance with CDC guidance are quite stringent (CDC Biosafety Level Criteria are included in Appendix A-1 to this EA). The EMBF is <u>not designed</u> to meet these BSL-3 criteria, is not being proposed for operation at the BSL-3 level, and would not be easy to retrofit to meet these criteria. Also, as noted earlier, all biological work conducted at LLNL must be reviewed by the Laboratory Biosafety Operations Committee (LBOC) and, when involving pathogenic organisms specifically, reviewed and approved by the IBC. Work that is not in conformance with federal regulations, CDC/NIH Guidelines, DOE Orders, and LLNL directives cannot be performed because it would not be approved by the IBC and would not be in conformance with provisions of the U.C. contract with DOE.

The term "weaponization" in reference to biological agents can be broadly defined as "the design, and production and storage in large quantity, of biological agents and their delivery systems for military purposes." This is not being done at LLNL, and is <u>not</u> a part of a DOE

proposal. Aerosol challenges do not imply "weaponization". An aerosol challenge is the method used to test a rodent by inhalation. The route of pathogen exposure affects the timing for onset of symptoms and it is the inhalation pathway that is one of the quickest. Aerosol challenge allows for testing of detection assays, treatment regimens, and medical intervention approaches as a consequence of inhalation exposures to pathogens. Nebulizers used for challenging test animals are frequently employed in private industry, including in the research and development of cosmetic products. The research proposed for the BSL-3 facility would involve growing and culturing agents, and in some cases challenging rodents by means of administering agents with a nebulizer. Again, no technology is being proposed, developed, or adapted at LLNL for the purpose of "weaponizing" agents.

LLNL has no intention, and would be prohibited under Title 18 of the U.S.C., of developing or producing biological materials for weapons use, often referred to in the media as "weaponizing". The prohibition against developing or producing biological agents for weapons is taken seriously at Livermore. All proposed research with pathogens, even non-select agents, regardless of the specific biological laboratory to be used is reviewed and evaluated in a multi-step process that ultimately requires directorate-level approval. This process is designed with checks and balances to ensure that scientific research is conducted legally, securely, within the staff's and the respective facilities' technical capabilities, and above all, as safely as possible. Conducting microbiological and toxin research at LLNL furthers the Biological and Toxin Weapons Convention (BTWC) goal of ensuring the security of potential biological weapon source material. The proposed LLNL facility would be one of the most secure BSL-3 facilities in the United States, and many times more secure that similar commercial facilities existing currently in the Bay Area or anywhere else in the world.

Because of the potential asymmetrical biological weapons threat, the United States is allowed, under the BTWC and U.S. Law, to conduct defensive bona fide *scientific research with potential biological weapon pathogens known as "select agents". This research would include what is known as "basic research" that could, for example, investigate the genetic linkage between Bacillus anthrasis (BA) and its "nearest neighbors" (e.g., B. cereus and B. thuringiensis) or examine genetic anomalies in the BA so-called "sub-specie" variants know as the Sterne and Vollum strains. Other research could, for example, process vegetative and spore cells to evaluate processes which might affect detection equipment's ability to identify genetic or chemical "markers" necessary to confirm the presence of microbial pathogens or toxins. Procedures or processes used to conduct this scientific research are the same or similar to those commonly used throughout biosafety laboratories in the government, public and private sectors. None of this research constitutes developing or producing biological materials for weapons use.*

Furthermore, LLNL has a major role in the CDC's Laboratory Response Network (LRN) to provide the highest level of analytical sophistication for purposes of identification and confirmation during disease outbreaks or bioterrorist attacks from suspected select agents. LLNL may also need to support other government agencies to provide forensic analysis to track down those suspected of perpetrating bioterrorist acts. Being able to accurately identify genetic or chemical attributes of microbial cells and toxins may be a crucial step in determining protective measures such as medical prophylaxis. As with the research that supports it, this capability would not constitute developing or producing biological materials for weapons.

The characterization of the potential inventory in the BSL-3 by several commenters is in error. LLNL has no plans to have 100 liters of a slurry of biological agents in any single laboratory at any one time. Most research involves a few milliliters of material in growth solution. LLNL plans to store samples of biological agents, including select agents, in small vials, most of which are 2 ml. The facility limit is 25,000 vials, so the maximum volume of the vials is closer to 50 liters, not 100 liters. Typically, less than 2 ml of sample is stored in any vial so the aggregate total volume of all samples would be significantly less than 50 liters. These vials are stored in -80 degree freezers in three separate laboratories in frozen form, not as aggregate liquid slurry. As noted above, only 1 liter would be handled in any laboratory at any one time.

The DOE does not operate a national biological research program. Individual research efforts are managed at DOE sites on behalf of non-DOE sponsors as "Work for Others". The DOE has established a Biosurity Executive Team, a national level working group, to recommend the establishment of biosurity-related policies, regulations, requirements, and standards. This comment will be forwarded to the Chairman of that group for consideration.

4. Compliance with Biological Weapons Convention

A commenter expressed concern that the proposed work would undermine the Biological Weapons Convention and be viewed with suspicion by the world community. Additionally, the commenter remarked that the draft EA gives no indication of how BWC compliance would be instituted. Several commenters were of the opinion that the draft EA does not provide a process to guarantee public scrutiny of the LLNL biosafety committee deliberations and decision making.

Several commenters reiterated concerns that research in this facility could be construed as violation of the Biological and Toxin Weapons Convention since it is located in a secure weapons laboratory and oversight by the Institutional Biosafety Committee (IBC) is less than "transparent".

Response

U.S. participation in the Biological Weapons Convention is discussed under topic 3 above.

The proposed BSL-3 facility would be operated according to all guidance and requirements established by such agencies as the CDC, NIH, USDA, DOE and LLNL. Specific guidance references are detailed in Section 2.1.2 of this EA. NIH guidelines require that an IBC be appointed by an institution to provide local and institutional oversight and approval of potentially hazardous lines of biological research (NIH 2001). Section IV-B-2 of the NIH guidelines establishes procedures that the IBC shall follow in its role of review and approval responsibility. These guidelines include review and approval of applications, proposals, and activities; and making available to the public, upon request, all IBC meeting minutes and any documents submitted to or received from funding agencies that those agencies must make available to the public. As detailed in this EA and in the NIH guidelines, at least two members of the IBC are not affiliated with LLNL and they represent the interest of the surrounding

community with respect to health and protection of the environment. These IBC members may be officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns of the community. Since the IBC is ultimately responsible for ensuring that research conducted at, or sponsored by, LLNL is in compliance with applicable guidelines or regulations, this ensures that the public will be involved in approval of BSL-3 research and review of safety and compliance protocol as it does now for certain BSL-2-level projects. It is possible that some specific project information will be subject to DOE security and classification restrictions, and will consequently not be made available to the public. All proposed microbiological research projects at LLNL, even projects with classified portions, will undergo review and approval by the IBC.

The IBC was established at LLNL in 1991 to ensure compliance with recognized guidelines and regulations concerning research with recombinant DNA or human, animal, and plant pathogens. In 1998, the IBC registered LLNL under the Laboratory Registration and Select Agent Transfer Program of CDC. As currently practiced at LLNL, the IBC must approve all research in the cited subject areas prior to commencement. Details regarding the procedures for choosing committee members and other IBC functions are not within the scope of this environmental review.

5. Public Health and Safety, and Worker Safety Issues

Comments regarding the issue of public health and safety ranged from general opposition to a BSL-3 facility at LLNL to specific concerns about the potential for accidents and the implementation of procedural safeguards. One commenter remarked that there was no evidence that LLNL conducted a preliminary hazards analysis for the proposed facility and another commenter stated that it was inappropriate to allow biological warfare agent research so close to a major population center. Commenters also expressed the opinion that anticipated work with genetically modified organisms would pose unique or unknown risks to the general public, emergency personnel, and regional medical workers. Commenters expressed concern about how LLNL would respond in the event of an accident at the BSL-3 and how the lab would notify the public and provide information on emergency response actions during an accident.

One commenter remarked that the Draft EA failed to address the effect that a release or exposure could have on the way a region functions. The commenter cited the anthrax attacks of 2001 as an example of the difficulties of determining the nature and extent of a hazard and the potential for entire facilities to close down, despite a relatively small number of casualties. One commenter stated an opinion that the immunization status of laboratory workers represents critical information that should be available to all employees of LLNL and residents of the area.

Comments on the Revised draft EA expressed concern that it does not adequately analyze the health impacts of a release of the the BSL-3 facility's total inventory of up to 100 liters or 25,000 different samples of pathogens.

Response

A Preliminary Authorization Basis Document (analogous to a preliminary hazard analysis) would be completed and approved by NNSA prior to the facility being constructed. A Final Authorization Basis Document (analogous to a final hazard analysis) will be completed and approved by NNSA prior to the facility becoming operational. As for emergency response, the scope and extent of emergency planning and preparedness at LLNL are based on, and commensurate with, the hazards and potential consequences associated with a facility and its operation. The Laboratory uses an emergency management system (known as the Incident Command System) that is capable of responding to and mitigating the consequences resulting from operational emergencies. Under this system LLNL coordinates with Livermore Police and Fire Departments who in turn notify the public during emergencies. The emergency management system also incorporates provisions and procedures for dialogue with and involvement of local area law enforcement, fire, emergency response agencies if necessary. Emergency response procedures are documented in the LLNL Environment, Safety & Health (ES&H) Manual. The requirements in the ES&H Manual are based on the Work Smart Standards (WSS) identified for the specific work and associated hazards and LLNL best practices that management has determined are requirements. The WSS set was derived from statutes, regulations, DOE Orders, and national and internally developed consensus standards. The ES&H Manual also describes the implementation of the ES&H management commitments made in the Laboratory's Integrated Safety Management System Description. Adherence to the requirements and processes described in the ES&H Manual ensures that safety documents across the Laboratory are developed and updated in a consistent manner.

NNSA is confident that the proposed BSL-3 facility at LLNL can be operated safely and securely.

The day-to-day functions of the proposed BSL-3 facility, and potential increase in the number of biological material shipments to and from the proposed BSL-3 facility do not portend a significant increase in the possibility of human health risks to workers or the public beyond those related to LLNL's current ongoing, routine, BSL-2-level activities.

The safe operation of over 250 BSL-3 facilities within the U.S. substantiates the analysis presented in this EA with regards to this issue. There are on the order of 40 BSL-3 facilities currently operating under the control of the University of California. Several of these are nearby at the UC San Francisco and UC Davis campuses. Representatives of the CDC are authorized to periodically inspect all BSL-3 facilities. When operational, CDC and NNSA would regularly inspect the BSL-3 facility at LLNL.

In reference to the immunization status of workers at LLNL, the information would be made available to proper authorities, such as the CDC. The immunization status of individual workers is part of their personal medical records and, as such, cannot be released to the general public. However, to reiterate from the EA (Section 2.1.2, Operations, pg 18), "Workers would be offered appropriate immunizations for the microorganisms being handled." Information about what immunizations are being offered to BSL-3 laboratory workers would be available from the regular meeting minute records of the IBC, as that pertains to controlling risk associated with proposed research. In the event of unusual epidemiological occurrences involving

communicable diseases, information about the medical condition of affected workers would be made readily available to CDC and other authorized public health officials.

As explained in Appendix C, section 3, the facility will not have 100 liters of pathogens available for release. It will likely take years, if ever, to approach the facility's 25,000 sample-vial physical storage limit. Also as stated earlier, volumetrically this accounts for less than 50 liters of material in a frozen state. Pathogens in the BSL-3 facility that are in liquid or slurry form would account for much less than the facility's 10-liter limit because of each individual BSL-3 laboratory's 1-liter liquid-slurry culture limit. This would be further reduced because each BSL-3 laboratory would not normally process volumes even close to the 1-liter restriction. Therefore, the release potential is consistent with the analysis of this EA.

6. Accident Analysis

Several commenters expressed the opinion that the Draft EA lacks a comprehensive analysis of earthquakes, and should address local and regional fault zones. Commenters called for a more thorough analysis of release possibilities and outcomes from seismic risks, as well as other natural disasters. One commenter expressed concern about the vulnerability of a prefabricated building versus that of a conventionally constructed building.

Several commenters pointed out that a 50-mile radius around LLNL embraces more than 7 million people as opposed to the 1.3 million stated in the Draft EA. Given the density and proximity of nearby populations, the commenters were of the opinion that the Draft EA lacked appropriate modeling for accidental releases. Commenters questioned the appropriateness of using accident scenario data related to operation of the U.S. Army Biological Defense Research Program (BDPR) or that of the existing BSL-2 labs operated by LLNL. The commenters stated that the U.S. Army has a long history of operating a BSL-3 facility, and neither DOE nor LLNL has comparable experience.

Commenters expressed the opinion that the Draft EA understated the potential risks of worker exposure, as well as subsequent potential risks of off-site transmission of diseases. Further, several commenters remarked that the process of aerosolizing agents could substantially increase the risk of release and exposure, especially in light of the quantity (up to one liter) of medium containing pathogens that would be permitted. Commenters were of the opinion that the Draft EA does not address the potential for failure of filter systems and called for a more complete analysis of the potential for HEPA filter failure. These commenters alleged that DOE has a poor record of maintenance with regard to operating HEPA filters in some of its nuclear facilities. Further, the commenters state that the Draft EA makes claims for the protective qualities of HEPA filters that exceed the documented record, citing DOE reports that the efficiency of HEPA filters for capture of particles in the 0.1 micron size range is less than the efficiency for the 0.3 micron-sized particles discussed in the Draft EA.

Commenters on the Revised Draft EA reiterated many of the opinions stated above regarding accident analysis. Commenters stated that that "new research by the USGS has determined there is a 62% chance that one or more magnitude 6.7 earthquakes will occur in the area within the

next 30 years", and "Other studies predict a quake with MM 10 shaking in the Livermore area (which is very violent – the scale is 1 to 10)." One commenter expressed an opinion that the maximum ground surface acceleration at return intervals of 500 and 1,000 years could be much greater that the values presented in the Draft EA of 0.38 g, and 0.65 g, respectively, and significant surface displacement is also possible. One commenter also cites the Parkfield Earthquake of 2004 which produced two recorded ground acceleration values of 1.13g and 1.31g as "evidence" that the evaluation of seismic hazards at the Livermore Site is in error. Many commenters noted that the BSL-3 Facility is located in the Bay Area which has a population of 7 million.

Commenters expressed concern regarding the testing and maintenance of HEPA filters and their potential for failure. One commenter claimed that "HEPA filters at LLNL are flimsy, weak, fiberglass, paper and glue structures mounted in wood or metal frames that can fail completely when wet, plugged, hot and over pressured from fires, explosions, blowers and even severe storms." and "even under optimal conditions, HEPA filters are unable to effectively contain all bio-agents measuring between 0.03 and 0.3 micrometers."

Response

The BSL-3 facility would incorporate design considerations for the occurrence of natural phenomena as appropriate for the LLNL site. The facility would be designed to the latest Performance Category 2 (PC-2) requirements of DOE Standard 1020-2002. Specifically, the seismic design would conform to the 2000 International Building Code, Seismic Use Group III, Criteria 2/3, MCE Ground Motion with an Importance Factor of 1.5. It would be operated under the requirements of LLNL ES&H Manual, Volume II, Part 10, Supplement 27.02, Earthquakes. According to Supplement 27.02, all structures over 5 feet in height must be seismically secured. Furthermore, incompatible materials must be segregated to mitigate spills that could cause chemical or biological releases, as well as fires or explosions due to chemical incompatibility.

Based on the 2002 seismic hazard evaluation for LLNL by J. B. Savy and W. Foxall, a 1.0g ground acceleration has a mean annual exceedance probability of $2x\ 10^{-4}$ (5000yr return interval). The probability that this (or a greater) ground motion will be experienced during the operational life of the BSL-3 facility (30yrs) is approximately 0.6%. To put this into perspective, the ground motion levels typically used for the design of standard buildings have a 10% exceedance probability over the presumed 50 year life of the facility (500 year return interval event) and an equivalent 5% exceedance probability over the life of high-hazard/toxic/critical facilities (1000 year return interval event). In NNSA's opinion, a 5% exceedance probability over the life of the BSL-3 facility would represent an acceleration level that may "reasonably" be expected to occur. For the BSL-3 facility, the ground motions used for design from the 2000 International Building Code (IBC), Seismic Use Group III, are 0.69g peak ground acceleration and 1.73g maximum spectral acceleration (a 1250 year return interval event), and would have an approximately 2.5% chance of being equaled or exceeded during its 30 year operational life. The "Maximum Considered Earthquake Ground Motions" specified for use in the 2000 IBC have been characterized by the Building Seismic Safety Council, as "the maximum level of earthquake ground shaking that is considered as reasonable to design structures to resist" (FEMA 303, 1997 edition, "NEHRP Recommended Provisions for Seismic Regulations for New Buildings and Other Structures", Part 2- Commentary).

The Parkfield Earthquake of 2004 produced two recorded ground acceleration values of 1.13g and 1.31g. However, accelerations in this range (and higher), at similar epicentral distances and from similar magnitude events are in fact included in the 2002 probabilistic seismic hazard analysis for LLNL by Savy and Foxall, and by the USGS in the determination of Maximum Considered Earthquake events, but have a low probability of occurring at LLNL. The 2002 seismic hazard study for LLNL indicates a mean estimate for a 1.31g ground motion occurring at the LLNL Site of approximately $5x10^{-5}$ annual probability of exceedance (an approximately 20,000yr return interval event). As such, this represents a level of conservatism in excess of that required for the seismic design of nuclear power plants (10,000 year return interval per ASCE 43-05 "Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities"). Furthermore, the occurrence of a single event on a distant fault system (approximately 180 miles from LLNL) should not form the basis for seismic design decisions at the Livermore Site.

There is no "recent history" of earthquakes in the area of LLNL producing ground motions at LLNL anywhere near this level observed for the Parkfield earthquake, which was a non-event for the Livermore site as it was approximately 180 miles distant. The 1989 Loma Prieta earthquake produced recorded ground accelerations at LLNL having a maximum value of approximately 0.15g. The maximum historic earthquake on the Greenville Fault (M5.8) occurred on January 24, 1980 (D.W. Carpenter, et al, August 1984)[1] and produced ground accelerations of approximately 0.3g at LLNL.

In NNSA's opinion, the Greenville Fault poses a "significant" but not "extreme" hazard to the Livermore site, and is not "easily" capable of producing severe earthquakes capable of serious damage to the proposed BSL-3 facility within its projected life, as the commenter suggests. The 2003 USGS Open-File Report 03-214 on "Earthquake Probabilities in the San Francisco Bay Region" gives only a 3% mean probability that the Greenville Fault will produce a major, damaging earthquake ($M \geq 6.7$) during the next 30 years, which in DOE's opinion does not rise to the level of an "extreme" earthquake hazard. The expected magnitude from a rupture of the entire length of either one or both segments of the Greenville faults is about 7 to 7.1. Such events are expected to produce Peak Ground Acceleration (PGA) values of about 0.5g at sites very close to the fault. Larger amplitudes are possible but not likely. For example, the attenuation model of Abrahamson and Silva (1997) predicts that there is less than a 10% chance of a ground motion as severe as 1g (PGA) even if a magnitude as large as 7 occurs on the Greenville fault. In any case, the earthquake hazard posed by the Greenville Fault, as well as other faults, is incorporated into the design parameters used for this facility.

The surface rupture that occurred during the 1980 Greenville earthquake did not occur within the LLNL site and surface rupture within the LLNL site would not be expected to occur in the event of future earthquakes. Studies to identify active faults in the vicinity of LLNL are described in Carpenter et al. (1984). These included literature reviews, photographic analyses, geologic mapping, shallow and deep borings, excavation of pits and trenches, and soil dating. The objective of these studies was to identify physical properties (e.g., location, length, dip) of the tectonic faults in the vicinity of LLNL, and to determine the likelihood of current seismic activity.

[1] May not be in the Revised EA

The result of these studies was that "No evidence of slip was found in all of the investigations for active faulting (within the last 300,000 years) within the LLNL Site", J.F. Scheimer, et al. (May 1991). Furthermore, the proposed location of the BSL-3 facility does not fall within the requirements of the Alquist-Priolo Special Studies Zones Act of 1972 which required the State Geologist to "delineate appropriately wide special studies zones to encompass all potentially and recently active traces of the San Andreas, Calaveras, Hayward, and San Jacinto Faults, and other faults, or segments thereof, as he deems sufficiently active and well-defined as to constitute a potential hazard to structures from surface faulting or fault creep."

The "activeness" of a fault is typically described in terms of earthquake recurrence relationships which express the expected number of earthquakes per year having magnitudes greater than some minimum value, and less than some maximum value. Recurrence relationships for fault sources are a function of long-term geologic slip rates, not number of aftershocks. The Greenville Fault has been assigned a slip rate of 2±1mm/yr in the USGS Open-File Report 03-214. This is a relatively low slip rate indicative of a low rate of fault activity as compared, for example, to the San Andreas Fault which has been assigned a slip rate of 17±4mm/yr to 24±3mm/yr (depending on segment) in the same report. This is a much higher slip rate and consistent with the greater level of seismic activity on the San Andreas Fault.

The description of potential damage to the BSL-3 Facility as a result of an earthquake is taken from FEMA 303 "1997 Edition, "NEHRP Recommended Provisions for Seismic Regulations for New Buildings and Other Structures, Part 2- Commentary", for buildings designed in accordance with the requirements for Group III structures subjected to the Design Ground Motion. Additionally, the seismic design provisions inherent in the 2000 IBC are intended to provide a margin of safety against the occurrence of larger, less probable earthquakes. As a minimum, a margin of about 1.5 times the design earthquake ground motion is provided. In other words, "if a structure experiences a level of ground motion 1.5 times the design level, the structure should have a low likelihood of collapse. This margin is dependent on the structure type, detailing requirements, etc., but the 1.5 factor is a conservative judgment appropriate for structures designed in accordance with the code provisions. Also, the Parkfield Earthquake report states that the damage experienced as a result of this earthquake, was only "minor nonstructural damage" (e.g., cracking of stucco and drywall, collapse of wood pile, broken windows, fallen bookcases, the separation of a timber canopy from a house, and a portion of an unreinforced masonry parapet wall collapsed). These were built with brittle materials (e.g. stucco and drywall). Structures that were designed or retrofitted for earthquakes showed minor to no damage. A masonry chimney that had been retrofitted by strapping it to the house showed no damage. Local bridges showed minor to no damage and were open with immediate occupancy post event. Buildings such as the BSL-3, with structural steel framing and bracing would have had negligible structural damage due to such an earthquake.

Personnel injuries at LLNL following the January 24, 1980 earthquake consisted primarily of lacerations, sprains, bruises, back problems, and other minor conditions that were treated by first aid. One employee suffered a heart attack while riding a bicycle an hour or so after the earthquake, and was treated at Livermore's Valley Memorial Hospital. Property damage at LLNL (initially estimated to be up to $10 million dollars) was actually less. No bricks fell from chimneys at LLNL as there were no brick chimneys at the Lab, and little damage was done to the

water lines. After the earthquake, main gas valves were closed and the main lines pressurized and checked for leaks. No leaks were found in the main system, although some leaks were found in building systems and were repaired.

Ground accelerations can be and often are amplified within the overlying building structure. This amplification effect is accounted for in the use of the 2000 International Building Code, Seismic Use Group III design criteria, which incorporates a design response spectrum having a spectral amplification factor of 2.5. It should be pointed out that the example given from the Geomatrix report is exceptionally conservative. A two percent damping level in a structure experiencing ground accelerations of 0.9g is unrealistically low. There is a wealth of data that shows that structures experiencing strong ground motion develop damping levels well in excess of two percent. A damping value of five to seven percent would be much more appropriate (and still conservative) for the BSL-3 structure at a 0.9g ground acceleration level. Increased damping would significantly reduce the maximum spectral accelerations experienced by the structure. For example, the maximum spectral acceleration of the Newmark-Hall median spectrum (NUREG CR-0098), anchored at a peak ground acceleration of 0.9g, at two percent, five percent, and seven percent of critical damping is 2.47g, 1.91g, and 1.70g respectively.

The BSL-3 facility is a safe facility, appropriately designed to withstand the effects of earthquakes, and the DOE Standards and Guides used to establish the Performance Category-2 design level for the BSL-3 facility were appropriately followed. The 2000 IBC Seismic Use Group III criteria is the appropriate design criteria for this facility per DOE Standard 1020-2002, and includes criteria for the design of facilities that house substances deemed to be hazardous to the public if they are released. The 2000 IBC utilizes ground motions for design that include the contributions to the site from all relevant earthquake sources, conservative factors of safety, and prescribed detailing requirements for ductility (toughness), to ensure the seismic safety of this facility in the event of a major earthquake. Additionally, the seismic design provisions inherent in the 2000 IBC are intended to provide a margin of safety against the occurrence of larger, less probable earthquakes. Based on these considerations, we believe the chance of any release of pathogens due to seismic activity to be exceptionally low.

In order to obtain a significant margin of safety a peak wind gust of 91 mph would be used as the design wind load, although it is an extremely unlikely event. Flooding is not a design consideration at the LLNL site, per the DOE's Final Environmental Impact Statement and Environmental Impact Report for the Continued Operation of Lawrence Livermore National Laboratory and Sandia National Laboratories, Livermore [DOE, 1992]. Prefabricated modular units, if used for the proposed BSL-3 facility, would be required to be constructed to standards equal to those for a permanent on-site constructed facility, including earthquake and ground motion standards.

The 2000 U.S. Census reports that Alameda County has a population of approximately 1.4 million people (Health Resources and Human Services [HRSA] 2000). The 2000 LLNL Environmental Report (LLNL 2001b) states that there are 6.9 million residents within an 80-km (approximately 50-miles) radius of the LLNL site. The EA will be changed to add the population of the 50-mile radius from LLNL.

The U.S. Army has been doing biological defense work for years, operating under the same safety protocol and CDC and NIH-developed guidelines as would be applicable at the proposed LLNL BSL-3 facility. This EA describes the Army's extensive experience working with hazardous infectious organisms and references their outstanding safety record to provide a perspective on the adequacy of following these guidelines in the safe operation of its facilities. The DOE has also been involved in biological defense research at LLNL and other facilities for years and has extensive BSL-2 facility experience. The BLS-2 laboratory staff at these facilities have safely handled many of the same agents that are proposed for handling in BSL-3 facilities. Highly trained individuals would operate the laboratory with modern equipment and in accordance with established nationally recognized guidelines and comprehensive oversight. Since 2000, LLNL researchers have safely worked with a number of strains of anthrax and plague at the BSL-2 level. The work has been conducted safely and in full compliance with all applicable security, health, and other administrative requirements and guidelines. NNSA is confident that DOE and LLNL have comprehensive and appropriate experience and trained personnel to safely operate the BSL-3 facility, and that potential risks to workers and non-workers have been adequately addressed in this EA.

The accident analysis scenario presented in the EA addresses the potential effects associated with an accident in which potential highly infectious cells would be disbursed into the environment from the proposed facility during its operation. Analysis of historical data related to the operation of other similar federal and industrial facilities shows that a significant release beyond the facility building is extremely unlikely to occur. The only releases that are probable would be contained within the building, which is a facility specifically designed for decontamination. Any accidental releases, if they occurred, would impact only a small area of the lab, which could easily be decontaminated. The likelihood of a wide area, city or population, effect should be considered improbable. The nature of the agents, dose/response potential, dispersion, the limited quantities involved, and the design of the building and safety protocols preclude a large-scale or widespread release potential. As described in the Draft EA, human pathogens for which there is no immunization or medical treatment available would not be handled in the proposed BSL-3 laboratory, in accordance with Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines.

In June 1999, LLNL imposed lifespan limits on HEPA filters, found in UCRL-AR-133354 Rev 1, "HEPA Filter and In-place Leak Testing Standard", of 10 years from date of manufacture if the filter is in a dry location or five years from date of manufacture or testing if it is where the filter could become wet, such as during a fire suppression system discharge. The HEPA filter installation proposed for the LLNL BSL-3 facility would be in accordance with accepted good practice for biological safety as specified in the nationally accepted criteria for biological safety, the Centers for Disease Control and Prevention/National Institutes of Health, Biosafety in Microbiological and Biomedical Laboratories (CDC 1999). Testing of HEPA filters in biological safety cabinets is part of the BSC certification and would be done in accordance with the National Sanitation Foundation (NSF International) Standard 49 as noted by the CDC (CDC 2000b). Performance testing of the HEPA filters would be conducted by NSF-accredited field certifiers.

NNSA acknowledged in the LLNL Supplement Analysis for Continued Operation of Lawrence Livermore National Laboratory and Sandia National Laboratories, Livermore (March 1999, DOE/EIS-0157-SA-01) the issue of reduced removal efficiency of HEPA filters for particles in the size range from 0.1 micron to 0.3 microns. The study which provided this information was from a dissertation written by Ronald C. Scripsick (Los Alamos National Laboratory Report, LA-12797-T, 1994). Even though the most penetrating particle size in his study was slightly smaller than the HEPA filter "most penetrating design point" of 0.3 microns, his results still showed a 99.97% removal efficiency or higher in the range from 0.148 to 0.196 microns. These removal efficiencies are higher than the removal efficiencies used for the accident scenario in this EA and therefore the scenario conclusions are unaffected by recognizing a smaller most penetrating particle size.

HEPA filters on the building HVAC exhaust system are not required by the CDC for biosafety level 3 laboratories. However, LLNL has installed these HEPA filters as an additional measure of protection. Besides HEPA filters on the BSCs, the building exhaust system has three sets of HEPA filters. Each set has two HEPA filters in series. Two sets are in use at any time, with the third available as standby. The facility control system monitors pressure differential across the prefilters and the facility HEPA filters. If the exhaust fans are unable to maintain a constant static pressure across the HEPA filters at a specified set point, the supply fan and the exhaust fans will shut down, and all bubble tight dampers will be closed. Building alarms would be activated and building staff would respond to shift exhaust to the unused HEPA filter set. During this response time, the second HEPA filter would remain intact. Therefore, the failure of one of the HEPA filters would not result in loss of containment. In the extremely unlikely event that both building HEPA filters failed, all BSL-3 laboratory activities would be suspended, materials placed in "safe mode," and the HVAC system would be shut down until the situation could be corrected. This would ensure that no pathogens could be released from the facility.

NNSA does not believe research conducted in the LLNL BSL-3 facility presents either a new or undue risk to the population of the San Francisco Bay Area or California, in general. As noted in the previous response to comments, BSL-3 laboratories currently operate in many other Bay Area locations and throughout California. BSL-3 laboratories are commonly located in these and other urban areas such as Atlanta, Georgia, Fredrick, Maryland, and Galveston, Texas. Even though work is performed in these laboratories with indigenous or exotic agents that may cause serious or potentially lethal disease through inhalation route exposure, just as would be performed at LLNL, these facilities do not pose any undue risk to the surrounding communities. As noted in the EA, NNSA is not aware of any incidents in the San Francisco Bay Area, California, or elsewhere in the United States of infectious materials released from catastrophic accidents at microbiological laboratories. No such event has occurred in the more than 50 years in which the military has been conducting biological defense research activities (DA 1989).

7. Threat of Terrorist Attack/Sabotage

Commenters expressed a general opinion that the Draft EA does not adequately address external or internal security issues, citing that no security analysis is included in the document. Concerns included the potential for unauthorized access, the potential for removal of biological agents by a

BSL-3 worker or other person, and the potential for a deliberate release of biological agents and subsequent risk to the surrounding community.

Commenters stated that the Draft EA does not address the possibility of terrorist attack, and in light of the September 11, 2001 events and anthrax mailings, consideration of terrorism and internal threats must be included in the NEPA analysis for the BSL-3 facility. One commenter stated an opinion that LLNL already represents a terrorist target and the addition of a BSL-3 facility, which the world may believe is for offensive research purposes, will exacerbate the threat of terrorism.

Commenters expressed many concerns regarding the adequacy of the terrorist assessment in the Revised Draft EA. Commenters expressed their opinion that the Ninth District Court ruling requires a full modeling of a release following a terrorist act and also a discussion of the public response measures. Several commenters doubted whether biological materials would be destroyed in a fire. Commenters expressed doubt about whether a terrorist would obtain biological materials from environmental samples if these materials were available in the concentrated or "milled" form they claim would be present in the BSL-3 facility. The adequacy of the building to withstand a terrorist attack and the competence of the security force were questioned by many commenters. One commenter doubted the EA's claim that stolen bioagents would not pose a serious risk to human health and safety citing the Anthrax Letter attacks in 2001. Another commenter questioned whether bleach would be kept in the same location as biological agents. In one commenter's opinion, freezers may pose a different type of environmental consequence and must be analyzed separately. One commenter expressed concerns that genetically modified organisms would have increased risk and survivability if there was an accidental release. Many commenters doubted the Revised Draft EAs assertion that the a release from the BSL-3 facility would pose a risk no greater than that posed from births of infected wild and domestic animals.

Many commenters stated their opinion that detailed evaluations of the consequences of terrorist acts must be conducted regardless of their probability of occurrence. Commenters suggest that it is possible to determine a general threat level for the facility. One commenter questioned why only three scenario's were chosen for evaluation. One commenter expressed concern that the "security concerns" prompting NNSA's removal of plutonium from LLNL should be considered in the EA. Many commenters expressed concern that locating a biological research facility at a nuclear weapons facility increased the likelihood of a terrorist attack.

In one commenter's opinion the Revised Draft EA "shirks genuine consideration of the impacts of terrorism by suggesting that because there are other BSL-3s in the U.S., the LLNL BSl-3 will not contribute much to an increased likelihood of an act of terrorism". The commenter compares this to a situation in which the Nuclear Regulatory Commission would avoid an in-depth review of the Diablo Canyon permitting action on the basis that there are other nuclear power plants in the country and so Diablo Canyon does not add much to the numeric likelihood of a terrorist attack.

Response

As stated in the EA, physical security and safeguards would be based upon a security analysis conducted during the appropriate project planning stage. As in all facilities managed at LLNL,

access is limited to only authorized DOE-badged personnel or under DOE-approved escort procedures. Safeguards would also be consistent with CDC/NIH guidelines. It would be imprudent to describe the specific security protocols in a public NEPA document as the commenter suggests. This is due in part to the relative high-security of the overall LLNL operations, and also to the limited and synoptic availability of significant quantities of viable pathogens due to the facility being focused on genetic research (on the parts of the microorganisms). Added to this is the extremely limited potential for a release of microorganisms from the multiple levels of bio-containment within the building. The level of security at LLNL and the uncertainty of available and viable microorganisms would preclude it from being a desirable or likely target for removal or theft of biological agents.

Historically, there have been at least two reasons why the potential results of terrorist attacks are not typically included in NEPA analyses. The first reason is that NEPA accident risk analysis is done for "reasonably foreseeable" accident events. While terrorist events are possible, these are not reasonably foreseeable accident events in the sense that a probability of occurrence could be determined for a NEPA analysis. This is not to say that NNSA does not evaluate possible terrorist actions and work to mitigate them. On the contrary, NNSA continuously strives to assess and remove potential threat opportunities. Secondly, regardless of the initiating event (whether naturally occurring, human-error, or malicious intent), the NEPA accident analysis scenarios presented in NEPA documents are generally bounding events for releases into the environment from the proposed facility.

Terrorist attacks come under the realm of security and therefore are appropriately evaluated in a separate risk assessment. That risk assessment would determine what security measures would be taken to protect the facility. This assessment document and its details are not available for public review since this would defeat the purpose by making all security measures public knowledge. Terrorists could then use this information to better plan for future attacks—something that no one wishes to facilitate.

NNSA believes that although a direct attack on the BSL-3 facility is possible using a commercial jet or a private aircraft, the result would be a fire that would destroy biological agents rather than dispersing them, and therefore it is not necessary to model such a release. An aircraft crashing into the proposed BSL-3 laboratory (the facility) could have different potential consequences depending on the scenario conditions, but would regardless result in the death of uncontained microorganisms. The range of conditions would be bounded by whether the aircraft were a larger-size jet or a much smaller propeller-driven aircraft. The former aircraft's size would demolish the facility and surrounding buildings on impact while the smaller plane might only cause a breach of containment. Fire would be a highly probable consequence under both conditions for reasons explained below. As will also be described, microorganisms whether vegetative cells or spores could not endure the temperatures of any fire resulting from these circumstances.

A large jet aircraft crashing into this facility would have the same result on impact regardless if the fuel tanks were full or nearly empty. Due to the plane's wingspan it would be almost impossible to not involve other surrounding buildings in the impact unless the plane approached from a nearly vertical angle. With fuel tanks full an aircraft impacting this facility would totally

demolish the structure (and surrounding buildings) in a conflagration nearly-reminiscent of the plane crashes into the World Trade Center towers or the Pentagon. The same aircraft crashing with fuel nearly exhausted would still break into flames due to ignition of fuel-vapor explosive gases released at impact. The only differences would be the amount of jet fuel burning at the impact site and the time it might take to extinguish the fire. Jet A fuel (>99% kerosene) would be the primary source of flammable material, but combustible materials from the plane and the building floors would become a secondary source. "Open pool" burning of kerosene produces temperatures approaching 1000 °C.

Alternatively, it would be possible to address the same conditions for a crash of a small aircraft fueled by aviation gasoline (Avgas). The difference with the Avgas (almost exclusively 100 Octane gasolines) is that it is even more ignitable than the jet fuel because of its physical and chemical properties. As noted on an Avgas Material Safety Data Sheet (MSDS) "this material is extremely flammable and can be ignited by heat, sparks, flames, or other sources of ignition" (Conoco Phillips, 23-May-2007). For example, Avgas has a much lower flash point, the lowest temperature at which a flammable vapor/air mixture exists at the surface above the fuel. The flashpoint for Avgas is less than -35 °F (-37 °C) while that of Jet A fuel is 100-150 °F (38-66 °C). While this crash wouldn't necessarily demolish the facility it would produce a fire. Flame temperature for gasoline (i.e., petrol) in an "open pool" fire (0.3 m diameter) is 1026 °C. (Drysdale, table 5.4, p. 165)

Fire or flames generate a great amount of heat at temperatures measured in the hundreds of degrees Celsius (°C) (Drysdale, 1998). Heat is lethal to all microorganisms and each has its own particular heat tolerance. Microbiologists have long recognized that bacterial spores are the most resistant life form, and therefore it would be expected that spores would be the most heat tolerant. In fact, the effectiveness of sterilization (the killing of all life forms) is measured by the ability to kill bacterial spores. Each microbial species (and form, vegetative cell and spore) has a thermal death time, or the time necessary for killing it at a given temperature. Each species also has a thermal death point, or the temperature at which it dies in a given time. These parameters are experimentally determined and used by the food processing industry to evaluate the microbial inactivation of foods. As expected, spores require higher temperatures and longer time periods for inactivation (US FDA, 2002). As the temperature is increased the amount of time necessary to sterilize with dry heat is decreased. Whitney et al. (2003) showed, for example, that Bacillus anthracis spores were sterilized with a dry heat in >90 minutes at 140 °C, 10 minutes at 160 °C, 2 minutes at 180 °C, 1 minute at 190 °C, and 30 seconds at 200 °C. Higher temperatures would significantly reduce the sterilization time even farther.

Because of their heat resistanc, microorganisms like Coxiella burnetii burnetii that form spore-like protective structures are killed at higher than normal pasteurization temperatures (63 °C for 30 minutes, or 72 °C for 15 seconds) (FDA, 2007). Mycobacterium paratuberculosis also demonstrates this heat resistance (62 °C for 14 minutes, and 71 °C for 78 seconds). However, neither would survive as long as bacterial spores in dry heat.

In all cases, virtually the entire inventory of pathogens in the BSL-3 facility would be contained in 2-mL double-containment plastic vials maintained in padlocked freezer/refrigerators. The vast majority of pathogen material not in freezer/refrigerators would be in other types of double-

walled containment. This would include, for example, incubators and centrifuges. The only instances of single or non-containment would occur in the biosafety cabinets (BSCs) where potential aerosol releases would be captured by the BSC airflow and filtration system. Pathogen-inoculated animals would be held in quarantine cages in cage racks with HEPA filtration. Single or non-contained pathogen materials would be in liquid or solid (e.g., agar media) form and not dried or powdered. Temperatures of only a few hundred degrees Celsius for seconds or a few short minutes would be all that is necessary to destroy these microbial materials. The minimum temperatures of a fire following any aircraft crash into these buildings would exceed that and for a much longer time.

LLNL would not have large quantities of "milled" concentrated biological agents as suggested by commenters, and would not have any overly-specialized equipment for delivering biological materials. LLNL has no intention, and would be prohibited under Title 18 of the U.S.C, of developing or producing biological materials for weapons use, often referred to in the media as "weaponizing". LLNL would not use the process of "milling", which commenters imply is a technique used to "weaponize" a biological agent. Research will include creating small volumes of liquid slurries that would be introduced as aerosol droplets into the lungs of mice using a nebulizer, which is a bench-scale device used to create an aerosol spray. Except during very brief intervals of mouse exposure, aerosolized material would not be present in the facility. Since nebulizers are common pieces of lab equipment and are commercially available, there would be no specialized equipment present in the facility that would be attractive to a terrorist, particularly since other commercially available equipment could also be used to create a similar, inhalable fine mist. The biological materials in the slurry or in sample vials are collected from growth media in very small amounts and are not considered to be highly concentrated. Accordingly, biological materials and equipment in the BSL-3 facility would have none of the characteristics that commenters claim would make them more attractive to a terrorist than similar materials found in other, less secure locations or in nature.

NNSA acknowledges that spores of organisms such as anthrax can survive in soils for extended periods of time. In fact, anthrax spores occur naturally in soils such as those in the Livermore area and the surrounding Altamont hills. Spores are known to survive for decades, as one commenter suggests. However, the presence of naturally occurring anthrax spores in local soils has not resulted in adverse health impacts. This reinforces NNSA's conclusion that the few spores present in a sample that survive after an accidental release from the BSL-3 facility would not pose a significant human health risk.

As stated in the Revised EA, NNSA considers the probability of a successful terrorist attack at the LLNL BSL-3 facility to be minimized to an extent commensurate with the potential threat. However, the Revised EA does include a discussion of consequences of terrorist acts, however unlikely. NNSA acknowledges in the EA) that, as with the Anthrax Letters of 2001, serious consequences and perhaps fatalities could occur following covert theft of select agents, modification and subsequent release in a setting that would result in human exposures. Because the potential release scenarios are limitless, there is no rationale for evaluating any specific scenario. NNSA does not believe that other scenarios that cause a significant breach in containment would result in a release of biological agents that would pose adverse health effects or require modeling.

The commenters do not provide any information to support their assertion that an insider could covertly obtain large amounts of "ready-to-use" biological agents. The analysis in the EA assumes that only a small amount of material would be obtained covertly by an employee since the employee would not want the theft to be discovered. An employee with unrestricted access could remove larger quantities of material. However, stealing larger quantities would defeat the covert nature of the theft since large numbers of missing material would not go unnoticed. Also, samples are stored in -80 degree freezers in 2 ml vials, not large amounts of "ready-to-use", aerosolized pathogens, as suggested by commenters. For these reasons, the EA assumes that covert theft would involve very small quantities of material that would require additional growth and preparation before they could be dispersed.

NNSA acknowledges in the Revised EA that theft of a select agent by an insider is within the realm of possibility. For this reason, LLNL has instituted programs to ensure that insiders whose backgrounds suggest they are at risk for engaging in unreliable, untrustworthy, or disloyal behavior are not allowed access to select agents. As stated in the Revised EA, only personnel on LLNL's CDC registration are allowed to handle these agents. In addition, UC also requires that personnel having access to select agents and toxins must enroll in and be approved by the LLNL Select Agent Human Reliability Program as described in the Revised EA. NNSA believes the personnel security policies and practices implemented for work with pathogenic agents at LLNL adequately protects against the covert theft of biological materials by employees.

The foremost mission of the LLNL Protective Force is to deal with possible terrorism scenarios. The Protective Force has developed plans, procedures and training to counter scenarios identified in the Biological Risk and Threat Assessment (BRTA) and has conducted several emergency drills in the BSL-3 Facility with facility staff. Recent evaluations by NNSA have found that the biological select agent and toxin research program at LLNL effectively implements emergency management and security programs in a manner that is commensurate with the risk. This includes the performance of the Protective Force. Accordingly, NNSA believes the physical security of the BSL-3 Facility provides appropriate protection against terrorist acts. The details of the Protective Force tactics and training are not appropriate for discussion in a public document. Revealing the measures in place could negatively impact the effectiveness of their procedures by providing terrorist information to better plan attacks. Also, as noted above in the response to comments on the original EA, LLNL is prohibited by law from discussing the details of the structural features or other physical precautions that have been taken to mitigate potential concerns identified in the BRTA.

Routine procedures for work with biological agents in biosafety cabinets require the presence of bleach to disinfect equipment and surfaces at the completion of work. Spilled bleach spreading in the BSC would kill any spilled biological agents. Bleach is not stored in the -80 degree freezers and would not kill any materials spilled from those freezers in such an attack. However, biological material frozen at -80 degrees is not in a dispersible form.

Regarding storage of biological materials in freezers, NSSA is unaware of any scenario involving a freezer that would be worse than other scenarios already analyzed in the Draft EA. Material stored in vials in -80 degree freezers is very non-dispersible even in the event of a

breach of one of the freezers. The commenter did not provide any additional information about how an accident involving a freezer would be any different or worse than other postulated accidents.

In regards to the comment comparing the LLNL BSL-3 and the Diablo Canyon Nuclear Plant, there are marked difference between the two situations that, in NNSA's opinion, render them distinct and different cases. Security is at a high level at all commercial nuclear plants in the United States. There is virtually no difference between the security at Diablo Canyon and any of the other 100 plus nuclear plants currently in operation. Security at the over 1300+ BSL-3 facilities in the United States, on the other hand, can vary widely between institutions. Since the BSL-3 Facility at Livermore is one of the most highly secure facilities anywhere in the world, NNSA believes the likelihood of direct attack is low. Also fuel in a form suitable for nuclear reactors is not found in nature as are the organisms to be studied in the BSL-3 facility. As such, there are a wide variety of potential natural sources for pathogens, as opposed to the very small number of sources for nuclear materials.

Commenters expressed the opinion that releases from the BSL-3 facility following catastrophic loss of containment cannot be compared to releases commonly observed during births in domestic herds of sheep, cattle and goats. NNSA believes that this comparison actually overstates the potential risk. NNSA directs commenters to a representative study published in the CDC "Emerging Infectious Diseases" publication titled "Wind in November, Q fever in December" (CDC, 2004). This study demonstrates human exposure from naturally occurring sources, in particular, Q fever transmission from animal reservoirs to humans by the inhalation of infected aerosols created during lambing season. C. burnetii does not form spores, but does form a spore-like small cell variant (SCV). Regions containing farms where outdoor birthing is common are considered a "potent source" of the C. burnetii SCV, according to this study, and windborne generation of aerosols is higher during the dry season. Persons living downwind from an extensive sheep-rearing area were shown to have an incidence of Q fever 5.4 times higher than that of a near-by urban area (CDC, 2004). Seventy three (73) cases of acute Q fever were diagnosed in a three-year period in this study area (however, even during this large outbreak, there were no fatalities) . As the EA notes, this is because concentrations of C burnetii organisms occur in birth fluids up to 10^{12}/g and birth products are left on the ground where they form a source of aerosols. By comparison, concentrations of organisms in samples in the BSL-3 Facility would normally be 10^{8}/ml and would not exceed 10^{10}/ml. Also, the samples would be in a frozen, non-dispersible form. As this example demonstrates, impacts of a release from the BSL-3 Facility following a catastrophic breach of containment would be less than those observed to occur downwind from areas with domestic livestock herds or other areas where these organisms occur naturally.

Reference: CDC 2004
"Wind in November, Q fever in December"
Hervé Tissot-Dupont, Marie-Antoinette Amadei,† Meyer Nezri,† and Didier Raoult**
Emerging Infectious Diseases
Vol 10, No. 7, July 2004
National Center for Infectious Diseases
Centers for DiseaseControl and Prevention

1600 Clifton Road, Mailstop D61,
Atlanta, GA 30333, USA.
http://www.cdc.gov/ncidod/eid/vol10no7/pdfs/Vol10No7.pdf

As noted on page 19, "Before any infectious microorganisms would be handled in the BSL-3 laboratories, the IBC and the researcher, in accordance with CDC guidance, would perform a risk analysis. LLNL occupational medicine and the local medical community would be informed of the microorganisms to be handled in the BSL-3 laboratories and would be aware of the methods of identification and control of associated diseases." This risk assessment and it's associated medical community awareness component is considered adequately protective by CDC prior to conduct of work with genetically modified materials.

LLNL implements security measures at LLNL for all programs, including the Superblock, commensurate with the threat. However, plutonium and highly enriched uranium are also managed by NNSA at multiple other sites in the NNSA weapons complex. Due to cost of security, NNSA has decided to consolidate these materials in fewer locations. This a cost-based decision that does not imply there is a level of security risk at LLNL that would warrant removal of biological materials.

Many commenters imply that co-location of biological research and nuclear research on the same site increases the likelihood that a terrorist act would occur because of the potential for a terrorist to obtain both nuclear and biological materials. Commenters do not suggest a scenario in which a terrorist would either try to destroy or breach both nuclear and biological facilities at the same time, or obtain both nuclear and biological materials. As stated in the revised Revised EA, NNSA considers the probability of either a direct attack on the BSL-3 Facility or a theft of biological materials to be very low. This assessment takes into consideration the co-location of the BSL-3 Facility with numerous other research facilities, including nuclear facilities.

8. TRANSPORTATION SAFETY

One commenter expressed concern about the safety of biological material shipments, especially traveling through the USPS, to and from the facility. The commenter stated that the EA does not adequately analyze the possibility of a shipment of pathogens being intercepted.

Comments on the Revised Draft EA received during the public comment period did not express any new concerns or provide information that was new and pertinent to transportation safety. However, DOE received additional comments after the public comment period regarding the shipping incident discussed in Section 4.2.2.3 of the EA, "Transportation Accident". In response, additional information about this incident was provided in Section 4.2.2.3.

Response
The volume of shipments of microorganisms into the proposed BSL-3 facility would increase when the facility first begins its operation, then would taper off to levels that are only marginally higher than are experienced today in support of existing and ongoing LLNL bioscience and health technology research. Shipments out of the facility would also represent only a slight increase over existing levels of biological shipments. Both incoming and outgoing shipments are

typically of milliliter- or micro liter-size samples packaged inside several layers of containment, per Department of Transportation (DOT) shipping requirements. The packaged samples are shipped via federal and commercial or private couriers and are tracked in accordance with nationally-accepted DOT and CDC requirements. Any increase in incidence of shipping accidents due to the incremental increase in the number of shipments to and from LLNL as a result of implementing the proposed BSL-3 facility would be negligible given the volume of mail and packages transported by these transport services. Similarly, any increase in vulnerability of biological agent shipments to terrorist seizure resulting from the incremental increase in shipments to or from LLNL would be negligible given the volume of mail and packages transported by these national-scale operations.

The EA notes that the shipment of samples to and from LLNL would involve materials packaged in accordance with DOT standards. The packaging required by DOT has already undergone extensive drop, crush, and other accident-condition testing, before DOT determined the safe and appropriate transport and packaging requirements for these types of samples. Using DOT standards for packaging and/or using couriers that transport the shipments according to DOT requirements does not result in an obligation by DOE to perform a unique NEPA review for transport of its materials through common carriers. Transportation of microbiological samples to and from various points around the country and around the world, when performed according to DOT standards for packaging and shipment, should result in no human health or environmental effects to the carriers themselves or to the public along the routes. Federal and commercial carriers have been transporting appropriately packaged biological samples for many years both before, during, and after the recent anthrax-contaminated letters were mailed. Hospitals, laboratories, schools, universities, and teaching facilities engage in the transport of biological samples in large numbers every day. Any increase in the risk of accident or terrorist attack because of shipments associated with the proposed BSL-3 facility at LLNL would be negligible.

9. PURPOSE AND NEED

A commenter expressed the opinion that the proposed action is not sufficiently justified in the "purpose and need" secton of the Draft EA. The commenter suggested that the DOE should look comprehensively at existing BSL-3 facilities and capabilities, so as not to duplicate capabilities by constructing a BSL-3 facility at LLNL. For example, the commenter questioned why the Draft EA did not discuss in more detail the option to conduct all the necessary BSL-3-level work at a BSL-3 facility currently used by LLNL (such as the CDC facility in Fort Collins) for its current projects. Additionally, commenters were of the opinion that the DOE is required to analyze whether the proposed Los Alamos National Laboratory (LANL) BSL-3 facility would provide an alternative to construction of the proposed facility at LLNL. Commenters questioned why it is necessary to have two BSL-3 facilities under the jurisdiction of the DOE, when BSL-3-level research could be done at one facility.

Comments on the Revised Draft EA did not express any new concerns or provide information that was new and pertinent to the purpose and need for the EA.

Response

LLNL conducts its own specific research, including understanding genetic and biochemical causes of disease, projects for countering biological terrorism, bioengineering research, and developing and applying computational biology capabilities. Many of these are unique to LLNL. Currently, DOE and NNSA research projects requiring BSL-3 sample preparation are contracted to universities or private sector laboratories. This procedure has increasingly become difficult and represents a barrier to continued efficient research for several reasons. Government and private sector projects requiring BSL-3-level facilities are on the rise, resulting in the existing laboratories being unable to accept as much outside work such as that represented by NNSA's/DOE's projects. Information security also needs to be carefully considered, since information associated with some samples requires a very high degree of physical security, which is not uniformly available through the use of contractor facilities. Additionally, scheduling difficulties at contract laboratories could seriously limit or compromise timely research projects. Quality assurance documentation, including chain of custody issues related to federal projects, are also essential to verifying data and interpreting results. It is critical to the research being conducted that the quality and security of samples not be compromised. If the DOE hopes to further the Nation's ability to detect and isolate microorganisms and treat victims of bioterrorism, enhanced capabilities are necessary at the location-centers for such research. For the reasons described above, the integrity of the research dictates that the BSL-3 facilities be under the direction of DOE, and the individual National Laboratory. It is not possible to continue conduct of all the BSL-3-level research in a timely, efficient, cost-effective, or security-controlled manner at another laboratory.

Although construction of the LANL BSL-3 facility recently began, it is not operational and won't be until it has met all readiness requirements. In addition, the research currently conducted at LLNL is different from that at LANL, and it is likely that each facility will continue to have separate areas of expertise. LLNL and LANL staff members would continue to collaborate on technical matters relating to their separate research and development efforts, as they have been doing in the past. For these reasons, DOE and NNSA believe that it is not duplicative to have two BSL-3 facilities under the jurisdiction of the DOE.

10. Adequacy of Alternatives Analysis

A commenter expressed the opinion that the discussion of alternatives in the Draft EA is deficient, stressing that a careful analysis of alternatives is essential due to the risks of placing such a laboratory in a densely populated urban area. According to the commenter, the EA addresses only various ways to construct a BSL-3 facility at LLNL but does not compare other possibilities for accomplishing the mission, such as using other existing facilities, using government facilities to be constructed in the near future, or constructing a BSL-3 facility at another DOE site.

One commenter claimed that the EA did not evaluate the consequences of the "No-action" alternative with respect to terrorist acts.

Response

The Draft EA presents a discussion of three different alternatives for construction and operation of a BSL-3 Facility at another National Security Laboratory or at the other locations at the Livermore Site or at Site 300 (Sections 2.5 through 2.5.3). The discussion of these alternative indicates that they do not meet the NNSA's purpose and need. Accordingly, these alternatives were not analyzed further in the EA.

The response to topic 5 above reviews the accident scenario and potential for risk to the local community. The response to topic 9 above addresses the need for a BSL-3 facility under the jurisdiction of DOE at LLNL, and discusses why the use of existing facilities located off-site (including potential BSL-3 facilities at other DOE sites) does not meet this need.

The Revised Draft EA did consider the impacts associated with a terrorist act under the "No-action" alternative. As noted on pages 63 and 64 of the Revised Draft EA, terrorist acts are possible under the No-action alternative, as evidenced by the 2001 Anthrax Letters. In NNSA's opinion, the proposed action does not measurably add to the avenues already available to a terrorist for obtaining pathogenic materials or measurably increase the likelihood of this type of malicious act. As stated on page 63, "Because a malicious individual could already obtain pathogenic material by other methods under the No-Action ("status quo") Alternative, the presence of pathogenic agents in the proposed, highly secured BSL-3 facility would not pose any new or greater risk to human health or the environment from an outside terrorist or terrorists than already accrues without operation of the BSL-3 facility at LLNL"

11. Waste Disposal

Commenters stated that although the Draft EA indicates that the proposed facility would direct 10,000 gallons of wastewater to the city sewage system, the EA does not adequately describe a monitoring system for the wastewater. Commenters questioned how LLNL would detect a "release" and how it would be prevented from being released into the city sewage treatment. The commenters expressed the opinion that since LLNL has had releases of toxic metals, radionuclides, and hazardous materials, a more thorough analysis of these issues should be undertaken.

One commenter remarked that the Draft EA was not clear on whether liquid waste materials generated from laboratory operations would be discharged directly to the sanitary sewer or first to retention tanks. The commenter points out that page 34 in the Draft EA states that liquid waste from the proposed facility operations would be discharged to a retention tank system, but page 45 states that there would be no retention tanks. The commenter also noted that discharge of waste from improperly characterized retention tanks to the sewer system has been a problem in the past at LLNL with radioactive and hazardous wastes, and suggested that discharge of toxins or pathogens to the sewer system is a possibility.

Similar comments were also raised concerning solid waste disposal. Commenters raised concerns about which area landfills would be used for non-hazardous solid waste and what analytical methods LLNL would employ to ensure that hazardous and infectious agents are not sent to the landfills.

Comments on the Revised Draft EA did not express any new concerns or provide information that was new and pertinent to waste disposal.

Response

As described in the LLNL Environmental Report 2000 (LLNL 2001b) made widely available to the public, LLNL achieved greater than 99% compliance with Livermore Water Reclamation Plant (LWRP) permit limits covering discharges into the sanitary sewer during 2000. During 2000, only three notices of violation were written (two for metals and one for cyanide) and no sewer releases exceeded discharge limits for radioactive materials. LLNL achieved between 99 percent and 100 percent compliance with permit discharge limits for 1996 through 2000.

All LLNL medical waste management operations comply with the California Medical Waste Management Act, which establishes a comprehensive program for regulating the management, transport, and treatment of medical wastes that contain substances that may potentially infect humans. In September 2000, an Alameda County Department of Environmental Health (ACDEH) inspection of the Biology and Biotechnology Research Program (BBRP) found no compliance issues or violations (LLNL 2001b). The Annual LLNL Environmental Reports for 1997-1999 state that inspections of LLNL's medical waste generator and treatment facilities also resulted in no compliance issues or violations. In 1996 the Alameda County Environmental Health Services Inspector issued only one report of violation for storage of medical waste (cotton swabs, bandages, and gauze pads) longer than 7days above 0° C. Immediately after the violation was received, a LLNL self-assessment of medical waste compliance was conducted, additional training was provided, and revised medical-waste management procedures were implemented.

Sanitary liquid waste would be generated from the proposed BSL-3 facility from research activities and from toilets, showers, and sinks. Soluble or liquid waste material generated from laboratory operations are expected to be about 3 gallons per week and would be treated with disinfectants prior to disposal in the laboratory sinks. As stated in the EA, no discharge limits currently exist for infectious materials that are commonly discharged by healthcare and veterinary facilities and laboratories or homes. However, liquid waste generated from the proposed BSL-3 operations would be discharged to a retention tank system for characterization and disinfection as needed prior to discharge to the sanitary sewer system. The incorrect statement on page 45 (no retention tanks) of the Draft EA has been removed. Discharge guidelines, monitoring, and applicable regulatory requirements and restrictions are described in Section 3.3.5 of the EA.

As described in Section 2.1.2 of the EA, all waste generated in the laboratories of the BSL-3 facility (including sample packaging, culture materials, petri dishes, personal protective equipment, and associated process wastes) would leave the laboratories only after decontamination in the autoclave and/or after being chemically sterilized. Waste sterilization

and quality assurance procedures for the autoclave are detailed in the EA. Live pathogen agents are not sent to landfills. No toxic metals, hazardous wastes, radiological waste, or hazardous chemical waste would be generated by the facility. Solid waste generated from the proposed facility would be sent to area landfills in the same manner as other BBRP and LLNL-produced solid waste. Any biological shipments sent from LLNL to other researchers or the CDC are decontaminated prior to shipment, as described in the EA.

12. TIMELINE FOR THE BSL-3 FACILITY

Commenters expressed the opinion that the timeline for construction of the LLNL BSL-3 facility, stated in the Draft EA as "...estimated to start in FY 2002 and take approximately 6 months to complete", indicates that the DOE is not serious about a good-faith NEPA review nor public involvement in decision-making. The commenter states that the 6-month construction period suggests that DOE has already decided to use a prefabricated building and the construction timeframe indicates a foregone conclusion and not a decision that is dependant on the NEPA review process.

Comments on the Revised Draft EA did not express any new concerns or provide information that was new and pertinent to the timeline for the BSL-3 facility.

Response

The proposed action in the Draft EA (a permanent modular unit constructed off-site and assembled on-site) is clearly described as the preferred alternative. CEQ and DOE NEPA regulations call for an EA to describe the Agency's preferred alternative, but this does not suggest that DOE has chosen this alternative, begun implementation of the alternative, or in any other way predetermined the results of the NEPA review process. The same is true for the projected construction schedule noted in the proposed action in the Draft EA. The dates and completion schedule outlined in the Draft EA were proposed schedules for the preferred alternative provided for illustrative purposes for the preferred alternative. Revised projected schedules for project completion are included in the Final EA.

13. OVERSIGHT

Commenter's expressed concern that NNSA does not provide adequate oversight for BSL-3 activities. Commenter's provided quotes from what they claim is the July 2005 IG Report 0695, including: "We concluded that there was insufficient organization, coordination, and direction in the Department's biological select agent activities. Specifically, the Department's activities lacked sufficient Federal oversight, consistent policy, and standardized implementing procedures, resulting in the potential for greater risk to workers and possibly others from exposure to biological select agents and select agent material maintained by the Department." Commenters request that NNSA describe how this report has been responded to and what is happening now regarding NNSA's efforts to coordinate select agent programs.

Response
The quotes are from the February 2001 IG report "Inspection of Department of Energy Activities Involving Biological Select Agents", and not from the July, 2005 IG Report 0695 as cited by the commenter. The July 2005 IG report included only 2 recommendations:

1. *An enduring entity should be created and empowered to coordinate biological select agent activities and issues across the DOE complex; and,*

2. *The Department should develop a corporate strategy for the establishment of biosafety level laboratories, to include determining the number and location of BSL-3 facilities, coordinating future construction funding, ensuring that work is not duplicated, and addressing associated safety and security issues.*

The DOE has concurred with both of these recommendations. As a fist step, a Biosurity Executive Team has been established. The charter of this Team is to recommend the establishment of biosurety-related policies, regulations, requirements, and standards. To address the second recommendation, the NNSA and the Office of Science have both committed to developing a corporate strategy for the establishment of biosafety level laboratories. However, it is beyond the scope of this document to review the potential impacts of a nationwide DOE Program.

14. PUBLIC COMMENT PERIOD AND PUBLIC HEARINGS

Commenters expressed their concern that DOE/NNSA has not given the public adequate time or opportunity to respond to the revised EA and requested the public comment period be extended for at least 45 additional days. In addition, commenters requested that DOE/NNSA hold public comment hearings in the impacted communities during the extended public comment period. Commenters claim that most area residents and other interested members of the public were not aware of the public comment period and that it was not widely publicized by the NNSA or LLNL.

Response
The DOE believes the extent of public participation opportunities for the Draft Revised Final EA has been appropriate and consistent with Federal regulations and DOE Policy.

The revised document was made available for a 30 day comment period beginning April 11 and ending May 11, 2007. The document was made available for review at the public libraries in Livermore and Tracy, at the public reading room at the LLNL site, and on the web at www-envirinfo.llnl.gov. A press release was issued announcing the availability of the document at the start of the comment period. This resulted in the information being communicated to the public through a variety of media. For example, the San Francisco Chronicle published an article on April 12, 2007 discussing the draft document. This article was made available on line and included links to the document. The Tracy Press published an article on April 13, 2007 and included the story on its website with a link to the document. The Tri-Valley Herald also published an article on April 12, 2007, and the Livermore Independent on April 19, 2007. A

local Television station, KTVU, reported on the availability of the document. In addition, the availability of the document was announced on the websites of several local public interest groups.

No comments received were excluded from the record. All comments were accepted even if they were received after the 30 day period.

This is the second opportunity for the public to comment on the substance of the document. The draft document was a revision of a previous document which had been publicly available for over 4 years. The revised document included only approximately 13 pages of new or revised text as compared to the previous version.

The DOE/NNSA believes the comment period was very successful. Over 80 comment responses were received from residents of 8 different states and the District of Columbia.

EXHIBIT 7

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

JOSEPH P. RUSSONIELLO
United States Attorney
CHARLES O'CONNOR
Assistant United States Attorney
450 Golden Gate Ave., Box 36055
San Francisco, CA 94102
Telephone: (415) 536-6967
Facsimile: (415) 436-6748

RONALD J. TENPAS
Assistant Attorney General
BARCLAY T. SAMFORD (NMBN 12323)
Trial Attorney
U.S. Department of Justice
Environment & Natural Resources Div.
1961 Stout St., 8th Floor
Denver, CO 80294
Telephone: (303) 844-1475
Facsimile: (303) 844-1350

Attorneys for Defendants

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

TRI-VALLEY CARES, MARYLIA KELLEY, JANIS KATE TURNER, and JEDIDJAH DE VRIES Plaintiffs, v. UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION, LAWRENCE LIVERMORE NATIONAL LABORATORY, Defendants.	Case No. 08-cv-1372-SBA DECLARATION OF LESLIE A. HOFHERR

I, Leslie A. Hofherr, declare as follows:

1. I am the Biosafety Officer for Lawrence Livermore National Laboratory (LLNL). I have held this position for the past 3 months. In my previous position I was the institutional biosafety officer for the University of California, San Francisco and UCLA. I have been in the environmental, health and safety field for 16 years and worked specifically with health and safety issues relating to biosafety level 3 facilities (BSL-3) for 16 years.

2. I have a BS in Bacteriology and Food Technology from Iowa State University, a master's in Food Technology from Iowa State University, and a Master's in Public Health from San Diego State University. I am registered biosafety professional and by examination certified as a specialist microbiologist and a certified biosafety professional.

3. Including my years of service at LLNL, I have 16 years of experience in the operation and management of BSL-3 facilities. My education and my work experience has provided me with a deep understanding of health and safety issues and requirements associated with biological laboratories, including BSL-3 facilities.

4. It is my responsibility to advise line management so they can ensure that LLNL's BSL-3 facility is ready to operate in a safe manner consistent with all applicable health and safety regulations. In that regard, I have for the past 3 months been intimately involved in all aspects of preparing the BSL-3 facility for operation. These activities include ensuring that all equipment installed in LLNL's BSL-3 facility meets BSL-3 requirements and operates as intended. It is my responsibility to advise line management on the training status of employees so that they can ensure that all personnel have been appropriately trained to the correct standards for working in a BSL-3 facility. Furthermore, I have reviewed and evaluated all the safety control measures that have been installed in the BSL-3 facility and can attest to the fact that they meet all the appropriate and applicable standards anal function as intended.

5. In my career as a health and safety professional, I have been responsible for health and safety issues relating to the operation of numerous BSL-3 laboratories. It is my professional opinion that LLNL's BSL-3 facility meets and exceeds all the applicable standards and requirements for a BSL-3 facility. For example, many BSL-3 facilities have only one High Efficiency Air Particulate (HEPA) system for ensuring that air is filtered before it is exhausted to the outside environment. LLNL's BSL-3 facility has a system whereby the exhausted air goes through at least two HEPA filters and in some instances the exhausted air must pass through three HEPA filters before it reaches the outside environment.

6. Furthermore, the BSL-3 facility will be constantly operated at negative pressure. Accordingly, in the extreme unlikely event that there is a breach in the structure of the facility, no materials from the facility will reach the external environment. Rather, the negative pressure will ensure that external air is pulled into the facility and exhausted after

passing through multiple HEPA filters.

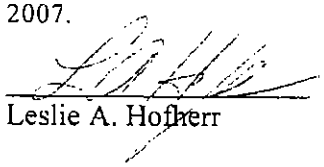
7. Similarly, many BSL-3 facilities allow their drainage system to drain into the regular sanitary sewer. In contrast, LLNL's BSL-3 facility will drain liquid waste to a holding tank to ensure that to the extent that any contamination is released in the drains, it will not reach the sanitary sewer, without first being disinfected. In addition, the BSL-3 facility has a state of the art vaporous hydrogen peroxide disinfection system. This system will allow the complete disinfection and destruction of all pathogens that may exist in the air or surfaces of the facility to be destroyed immediately with the push of a button.

8. In my experience as a seasoned health and safety professional for biological laboratories, I have yet to see an example of a BSL-3 facility that has been better designed or more closely scrutinized for every conceivable safety or health issue as LLNL's BSL-3 facility. The design and construction of the BSL-3 facility, the installation of the very best equipment, the use of redundant safety systems and the comprehensive and extensive training required of workers who will utilize the facility leads me to believe that LLNL's BSL-3 facility will operate in a completely safe and proper manner.

9. Similarly, the select agents that may be used in the BSL-3 facility are no different than the select agents, in kind or concentration, that are used in BSL-3 facilities that exist at universities and hospitals that are located throughout the San Francisco Bay Area. Furthermore, the type of work that is being proposed is similar to the types of work that occur in other local BSL-3 facilities. These other BSL-3 facilities have been operating in the local area for many years without any adverse impact on the population.

10. Work in the BSL-3 facility that involves select agents will be subject to all the appropriate work process controls and use of all applicable and appropriate safety equipment. All personnel will be trained in working in a BSL-3 facility and the associated work process controls and safety procedures and equipment. The concentrations of select agents that will be used in the BSL-3 facility are such that even in the unlikely event that materials escape the biosafety cabinets, where most if not all such work will occur, such material will then have to pass through at least two other HEPA filters before reaching the external environment. Even if such an incredibly unlikely event should occur, the concentrations of the select agents being used are such that the ambient air would dilute the select agent to the point that its hazard would be negated.

I declare under penalty of perjury that the foregoing facts are true to the best of my personal knowledge, that the conclusions expressed above reflect my best personal judgment. This declaration was executed in Livermore, California, on March 20. 2007.



Leslie A. Hofherr

EXHIBIT 8

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

National Environmental Policy Act

N E P A

RECOMMENDATIONS for ANALYZING ACCIDENTS under the NATIONAL ENVIRONMENTAL POLICY ACT

July 2002

U.S. Department of Energy
Environment, Safety and Health
Office of NEPA Policy and Compliance

United States Government **Department of Energy**

memorandum

DATE: July 10, 2002

REPLY TO ATTN OF: Office of NEPA Policy and Compliance, EH-42:Cohen:202-586-7684

SUBJECT: Final Guidance on Accident Analyses under NEPA

TO: Secretarial Officers and Heads of Field Organizations (list attached)

I am pleased to provide the attached guidance entitled *Recommendations for Analyzing Accidents under NEPA*, which my staff prepared with help from your National Environmental Policy Act (NEPA) Compliance Officers and in consultation with the Office of General Counsel. We expect that this guidance will foster consistency among NEPA documents while providing document preparers with substantial flexibility in approach.

The guidance clarifies and supplements *Recommendations for the Preparation of Environmental Assessments and Environmental Impact Statements*, which the Office of Environment, Safety and Health issued in May 1993. This new guidance focuses on principles of accident analyses under NEPA and presumes that accident analysts have appropriate technical knowledge and skills. The guidance addresses many key aspects of analysis but is not comprehensive; we intend to issue further topical supplements as appropriate.

In preparing this final guidance, we responded to comments from NEPA Compliance Officers and other members of the Department's NEPA community on draft guidance that we circulated in April 2000. We provided NEPA Compliance Officers with a detailed response to comments on the draft guidance and an opportunity, in June 2002, to review a preliminary draft of the final guidance; we have considered their recent comments on the preliminary draft of the final guidance. Questions regarding *Recommendations for Analyzing Accidents under NEPA* should be directed to Eric Cohen in the Office of NEPA Policy and Compliance at 202-586-7684 (eric.cohen@eh.doe.gov).

Beverly Cook
Assistant Secretary
Environment, Safety and Health

Attachment
cc: Distribution List

Recommendations

for

Analyzing Accidents under NEPA

Contents

Recommendations

for

Analyzing Accidents under NEPA

1.0 Introduction

This paper provides guidance for preparing accident analyses in Department of Energy (DOE) National Environmental Policy Act (NEPA) environmental impact statements (EISs) and environmental assessments (EAs). This guidance clarifies and supplements *Recommendations for the Preparation of Environmental Assessments and Environmental Impact Statements* (*Recommendations*), which the Office of Environment, Safety and Health issued in May 1993 (DOE, 1993). For convenience, Section 6.4 (accident analysis) of *Recommendations* is attached to this guidance (Attachment 3).

This guidance addresses NEPA policy and requirements related to accident analyses in NEPA documents, and is targeted primarily to those responsible for preparing NEPA documents, including NEPA Document Managers, NEPA Compliance Officers, and document reviewers. This guidance does not provide detailed technical instructions for analysis of accidents; it presumes that accident analysts have appropriate technical knowledge and skills.

Further, this guidance addresses only certain aspects of accident analyses. The Office of Environment, Safety and Health intends to issue topical supplements to this guidance.

As with all aspects of environmental documentation, appropriate security reviews of accident analyses under NEPA should be conducted to determine whether public access to information should be limited.

1.1 Definition

An accident is an unplanned event or sequence of events that results in undesirable consequences. Accidents may be caused by equipment malfunction, human error, or natural phenomena.

1.2 Purpose

Documents prepared under NEPA should inform the decision maker and the public about the chances that reasonably foreseeable accidents associated with proposed actions and alternatives could occur, and about their potential adverse consequences. The term “reasonably foreseeable” extends to events that may have catastrophic consequences, even if their

probability of occurrence is low, provided that the analysis of the impacts is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason. [Council on Environmental Quality (CEQ) NEPA Regulations, 40 CFR 1502.22]

Accident analyses are necessary for a reasoned choice among the proposed action and alternatives and appropriate consideration of mitigation measures. Accident analyses in NEPA documents can provide estimates of the magnitude of risk[1] that the proposed action and alternatives would present and a comparison of risk among the proposed action and alternatives.

1.3 Sliding Scale

Consistent with the principle that impacts be discussed in proportion to their significance (40 CFR 1502.2(b)), DOE NEPA document preparers should use a sliding scale approach (as described in *Recommendations*) to accident analyses. While this paper provides general principles to guide the development of accident analyses for DOE NEPA documents, these principles do not reduce to a "cookbook" approach. Rather, DOE document preparers must apply considerable judgment to determine the appropriate scope and analytical requirements of accident analyses for each DOE NEPA document. For example, preparers will need to determine the appropriate range and number of accident scenarios to consider, and the level of analytical detail and degree of conservatism that should be applied. A sliding scale approach is particularly applicable in making these determinations.

Key factors to consider in applying a sliding scale approach to accident analyses include:

- probability that accidents will occur
- severity of the potential accident consequences
- context of the proposed action and alternatives
- degree of uncertainty regarding the analyses (e.g., whether sufficient engineering design information is available to support detailed analysis) and
- level of technical controversy regarding the potential impacts.

[1] Although "risk" is a term that can be used to express the general concept that an adverse effect could occur, in quantitative assessments it is generally understood within DOE to refer to the numeric product of the probability and consequences. "Risk" is used in the latter way in this guidance. When risk cannot be quantified, it is appropriate to discuss risk qualitatively in terms of the probability and potential consequences.

2.0 Overview

An accident is an event or sequence of events that is not intended to happen, and indeed may not happen during the course of operations. The probability that a given accident will occur within a given time frame can be estimated. The probability of occurrence is expressed as a number between 0 (no chance of occurring) and 1 (certain to occur). Alternatively, instead of probability of occurrence, one can specify the frequency of occurrence (e.g., once in 200 years, which also can be expressed as 0.005 times per year).

An accident *scenario* is the sequence of events, starting with an *initiating event,* that makes up the "accident." It is important to distinguish the probability (or frequency) of the initiating event from that of the entire scenario; the probability of the entire scenario is of primary interest in NEPA accident analyses because it expresses the chance (or rate) that the environmental consequences could occur.

In this guidance the environmental consequences of accidents are effects (impacts) on human health and the environment. In discussing an accident's effects on human health in NEPA documents, it is both conventional and adequately informative to consider three categories of people: involved workers, noninvolved workers, and the general public. For each of these categories, evaluate impacts on the maximally exposed individuals and the collective impact to each population group. As noted in *Recommendations*, the analysis of human health effects should be carried to completion. That is, do not report only doses (radiological and chemical, as appropriate) to individuals and groups, which are neither health effects nor environmental impacts. Rather, identify and quantify, when appropriate, potential health effects (e.g., number of latent cancer fatalities).

- ✓ Evaluate impacts for: involved workers, noninvolved workers, and the general public.
- ✓ Evaluate impacts on the maximally exposed individual in each category and the collective impact to each population.
- ✓ The environment includes biota and environmental media, such as land and water.

In the context of analyzing accidents, the environment includes biota and environmental media, such as land and water, which may become contaminated as the result of an accident. This guidance refers to effects on biota as ecological impacts.

DOE's accident analyses under NEPA should consider both radiological and non-radiological hazards, commensurate with significance. Some DOE NEPA documents have focused too much on potential radiological accidents in comparison with non-radiological accidents. In many cases the risks associated with potential releases of toxic chemicals may be far greater than radiological risks, and should be analyzed accordingly. For example, many DOE sites provide their own potable or wastewater treatment, which can require storing significant quantities of chlorine, an extremely hazardous substance. *Recommendations* (Section 6.2, "Human Health Effects") discusses the analysis of effects from chemical exposure.

With respect to radiological risks, note that the discussion of *Human Health Effects* in *Recommendations* focuses on the effects of low doses of radiation. However, an accident analysis may involve both high and low radiation doses. High absorbed doses (hundreds of rad) delivered over a short period of time may result in a risk of a prompt fatality from non-cancer syndromes (e.g., gastrointestinal syndrome, pulmonary syndrome, or hematopoietic syndrome). Evans et al. (NRC, 1993) provides methods for estimating these early mortality risks.

- ✓ Consider both radiological and non-radiological hazards, commensurate with significance.
- ✓ Use appropriate current dose-to-risk conversion factors that have been adopted by cognizant health and environmental protection agencies.

In addition, the appropriate dose-to-risk conversion factors for estimating impacts at high doses (between about 25 and 100 rem) may not be appropriate at lower doses (less than about 25 rem). For example, the high-dose-to-risk conversion factor in Federal Guidance Report No. 13 (EPA, 1999) is 1.1×10^{-3} fatal cancers per rem; the corresponding low-dose-to-risk conversion factor is 6×10^{-4} fatal cancers per rem. As discussed in *Recommendations*, use current dose-to-risk conversion factors that have been adopted by cognizant health and environmental protection agencies, such as the Environmental Protection Agency and the Nuclear Regulatory Commission. When uncertain, consult the Office of Environment, Safety and Health.

In presenting accident analysis results, be clear about the types of exposure scenarios analyzed to avoid confusion. For example, radiological accident scenarios often involve inhaled or ingested long-lived radioactive materials that result in a persistent dose rate to a person throughout his/her lifetime, the accumulation of which is expressed as a committed effective dose equivalent. The reported committed effective dose equivalent may be a large number (e.g., several hundred rem) that may appear to be a high *acute absorbed* dose. In presenting the results for such scenarios it is important to associate the estimate of committed effective dose equivalent with a time period starting from the exposure event and continuing through the person's lifetime.

3.0 Accident Scenarios and Associated Probabilities/Frequencies

3.1 Scenario Development

Range of Accident Scenarios

The key to informative accident analyses is to develop realistic accident scenarios that address a reasonable range of event probabilities and consequences. The set of accident scenarios considered should serve to inform the decision maker and the public of the accident risks associated with a proposed action and alternatives. DOE should consider accident scenarios that represent the range or "spectrum" of reasonably foreseeable accidents, including low

probability/high consequence accidents and higher probability/(usually) lower consequence accidents. (Attachment 1 discusses a related issue, namely intentional destructive acts.)

Analyze *maximum reasonably foreseeable accidents* to represent potential accidents at the high consequence end of the spectrum. A maximum reasonably foreseeable accident is an accident with the most severe consequences that can reasonably be expected to occur for a given proposal.[2] Such accidents usually have very low probabilities of occurrence. As noted above, however, the accident analysis normally should not end with the analysis of maximum reasonably foreseeable accidents.[3]

For most proposals, DOE also should analyze other accidents in the "spectrum" because they may contribute importantly to, or even dominate, the accident risks. In some cases other accidents along the spectrum with lesser consequences than the maximum reasonably foreseeable accident may have an associated significant risk, perhaps a greater risk than the maximum reasonably foreseeable accident. The Cerro Grande fire (see text box on page 8) is an example of such an accident. Analyze a sufficient range of accidents to adequately inform about the accident risks of the proposed action and alternatives.

- ✓ Analyze the consequences of maximum reasonably foreseeable accidents.
- ✓ Analyze a sufficient range of accidents to adequately inform about the accident risks of a proposed action and alternatives.
- ✓ "Bounding" approaches may be used to streamline analyses and account for uncertainty, but tend to mask differences among alternatives.

In developing accident scenarios, some document preparers compensate for analytical uncertainty by using conservative or "bounding" approaches that tend to overestimate potential impacts. Bounding approaches based on conservative assumptions may have several potential benefits, such as streamlining an analysis when there are many uncertainties and avoiding the need to prepare more realistic analyses when not warranted. Further, bounding analyses may be more defensible than more realistic approaches because they are unlikely to underestimate potential accident consequences. On the other hand, bounding analyses may mask differences among alternatives and be less informative about the potential need for mitigation. Also, excessive conservatism may result in a misleading presentation of accident risks.

Because one purpose of NEPA analysis is to inform the public, consider analyzing an accident scenario in which the public has expressed a keen interest, even when the scenario is not

[2] Maximum reasonably foreseeable accidents are not the same as "worst-case" accidents, which almost always include scenarios so remote or speculative that they are not reasonably foreseeable and not helpful to a decision maker. Analysis of worst-case accidents is not required under NEPA.

[3] An exception to these general guidelines may exist in circumstances where the consequences of the maximum reasonably foreseeable accident are very small. In that case, analyzing only the maximum reasonably foreseeable accident may provide sufficient information regarding the accident risks of the proposal.

reasonably foreseeable. Do not analyze physically impossible accidents, however. Always explain why a scenario of interest to the public was excluded from analysis.

Scenario Probabilities

An accident scenario involves a postulated initiating event followed by a sequence of other events or circumstances that result in adverse consequences. If these subsequent events always occur when the initiating event occurs (i.e., the subsequent events have a conditional probability of 1, given that the initiating event occurs), then the probability (or frequency) of the entire accident scenario is that of the initiating event. Otherwise, the scenario probability would be the product of the initiating event probability and the conditional probabilities of the subsequent (presumed independent for purposes here) events, given that the initiating event has occurred.

Conservatisms

In accident analyses, as with many aspects of environmental analysis in NEPA documents, preparers need to make judgments about the appropriate degree of conservatism to apply. In applying the sliding scale principle to making such judgments, preparers should consider the fundamental purposes of the analysis as discussed above, the degree of uncertainty regarding the proposal and its potential impacts (see further discussion of uncertainty below), and the degree of technical controversy. Accident analyses under NEPA should be realistic enough to be informative and technically defensible.

Consistent with CEQ regulations, avoid scenarios that are based on pure conjecture (40 CFR 1502.22). Specifically, avoid compounding conservatisms – evaluating a scenario by using conservative values for multiple parameters will yield unrealistic results.

- ✓ Apply the sliding-scale principle in making judgments about the appropriate degree of conservatism.
- ✓ Avoid scenarios that are based on pure conjecture (40 CFR 1502.22).

For example, in air dispersion modeling, it is nearly always unrealistic to assume only extremely unfavorable meteorological conditions; prevailing (median) meteorological conditions generally should be used. In exceptional cases (e.g., when there is heightened controversy regarding accident risks or to enable a comparison with analysis in another document), it would be appropriate to estimate and present accident consequences for both median conditions and unfavorable conditions. Median conditions are often defined by using 50% meteorology, which represents plume concentrations that are not exceeded 50% of the time for a given direction and distance or receptor location, and are often characterized by stability class D and moderate wind speeds. (Fifty percent meteorology should not be confused with annual average meteorology. The latter is appropriate for estimating the impacts of normal operations or expected occurrences, but is generally not appropriate for estimating the consequences of accidents.) Unfavorable conditions

are often defined using 95% meteorology,[4] which represents plume concentrations that are not exceeded 95% of the time, and are often characterized by stability class F and low wind speeds. (However, when estimating plume concentrations from elevated releases, both median and unfavorable conditions may be characterized by other combinations of stability class and wind speed.)

Similarly, using estimates of plume centerline concentrations may be appropriate for evaluating impacts to maximally exposed individuals, but would not be appropriate for evaluating population impacts (would overestimate impacts); sector-averaged plume concentrations would yield more realistic results for population impacts. In other words, it would be unrealistic to assume that everyone in a population received the same exposure as the maximally exposed individual. (As appropriate for the constituents released during an accident, realistic plume concentrations may be based on time-integrated concentrations or peak concentrations, or they may incorporate averaging times.)

Applying these principles to choices of other key parameters will help avoid unrealistic results.

[Note: It would never be appropriate to assume only extremely unfavorable meteorological conditions for the purpose of reducing estimates of the probability of an otherwise credible accident scenario, and then fail to analyze the scenario at all because, by taking account of the probability of unfavorable meteorological conditions, estimates of the overall scenario probability are then judged to be so low as to be not reasonably foreseeable. Although meteorological conditions affect the consequences of accidents, the probability of meteorological conditions assumed in air dispersion modeling should not be included in estimates of the probability of an accident scenario analyzed in a NEPA document. In those cases when document preparers choose to present accident consequence estimates based on both median and unfavorable meteorological conditions, it would be appropriate to note that the unfavorable conditions would be less likely to occur.]

3.2 Frequency

“Frequency” refers generally to the *rate* at which events occur or are expected to occur over some measured interval (e.g., number of events per unit time, number of events per operation, or number of events per mile traveled). In this guidance, frequency refers to the number of accident events expected per year. “Return period” is a related concept, applicable to natural phenomena (e.g., earthquakes, storms, high winds, and floods). An event with an expected return period of 100 years (e.g., a 100-year flood) is defined to have a frequency of occurrence of one event per 100 years, or 10^{-2} per year.

[4] Unfavorable atmospheric conditions also have been defined by 99.5% sector-specific and 95% overall site meteorology [e.g., see Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants (NRC, 1983)]. Ninety-five percent overall site meteorology is different from 95% meteorology in that 95% overall site meteorology is determined based on the distance to receptor locations in all directions, while 95% meteorology is based on a single direction or single receptor location.

Case Study – LANL SWEIS Wildfire Scenario

The accident analysis in the Final Site-wide EIS (SWEIS) for the Los Alamos National Laboratory (LANL) (DOE-EIS/0238, January 1999) helped reduce the consequences of the Cerro Grande wildfire that burned about 9,000 acres (about 30 percent) of LANL, and about 50,000 acres of surrounding land, in May 2000. The SWEIS analysis proved to be realistic – a wildfire scenario analyzed closely mirrored the actual event – and the SWEIS was a helpful resource during and after the fire. Further, the document prompted the Department to take action beforehand to mitigate potential wildfire consequences, which helped protect buildings in the path of the fire from damage. The only serious property damage within LANL was to temporary structures, such as trailers, that were destroyed.

The Draft SWEIS did not analyze a site-wide wildfire scenario. Rather, the Draft SWEIS considered fires at individual facilities but did not analyze such fires in detail because they were bounded by other facility accidents. Comments at a public hearing from a forester at the nearby Santa Fe National Forest and written comments from the Department of the Interior focused attention on wildfire, and the SWEIS team promptly investigated. In view of the high annual probability of a wildfire, estimated in the Final SWEIS at about 0. 1 (once every 10 years), the team determined that potential wildfires were among the risk-dominant accident scenarios for LANL, warranting immediate mitigation measures.

As a result of the SWEIS analysis and the dedication of the document preparation team, mitigation was begun immediately to reduce the wildfire risks at key facilities, including waste facilities at TA-54 and the Weapons Engineering Tritium Facility at TA-16. DOE removed trees and other potential fuel, including replacing wooden pallets with aluminum ones. (See “Los Alamos Site-wide EIS Analyzed Wildfire Impacts, Prompted Mitigation Actions,” *Lessons Learned Quarterly Report*, June 2000, page 1, available on the DOE NEPA Web at http://tis.eh.doe.gov/nepa, under NEPA Process Information.)

The potential radiological consequences of a wildfire, as estimated in the Final SWEIS (0.34 LCFs), were small in comparison with those of postulated earthquakes. The SWEIS analyzed several earthquake scenarios, with estimated consequences ranging from about 16 LCFs (moderate event that damages some facilities, estimated to occur once in 350 years) to about 230 LCFs (a very large event that damages all facilities, estimated to occur less than once in about 33,000 years). Accounting for probabilities of occurrence, however, the estimated radiological risks of a wildfire (0.034 LCFs per year) were greater than for the very large earthquake (0.0095 LCFs per year), and less than a moderate earthquake (0.046 LCFs per year).

Moreover, the non-radiological consequences of the Cerro Grande wildfire were devastating for the people impacted. This illustrates that, as with many accident scenarios, a single risk calculation or pathway does not encompass all of the impacts. Importantly, the SWEIS evaluated potential hazards other than radiation exposure. For example, the Final SWEIS supplemented the discussion of radiation-related human health impacts with a discussion of potential chemical releases, loss of protective cover, soil erosion, runoff, effects on biological systems and cultural resources, effects on legacy contaminants, and other consequences of a wildfire.

This case study illustrates several key points, including the importance of:

- Analyzing a sufficient range of accidents to adequately inform about accident risks
- Considering non-radiological impacts
- Using accident analyses to identify potential mitigation measures, and
- Considering input from the public and other government agencies.

While frequency is a useful quantity in accident analyses, it is not a "bottom line" measurement. Rather, the bottom line measurement is the probability that the accident would occur during the lifetime of the proposed action. For example, the probability that an event with a frequency of 1x 10^{-6} per year would occur during an assumed 30-year project lifetime is about 3 x 10^{-5} [about 30 times 10^{-6}].[5] Both frequency (or return period) and the probability of occurrence during the lifetime of the proposed action should be reported in NEPA documents.

Most facilities have operational lifetimes of only several decades. Accident scenarios that have frequencies less than 10^{-6} per year are so unlikely to occur during the life of such facilities that they generally are not important to consider in making decisions about the facilities. Nevertheless, scenarios with frequencies in the range of 10^{-6} to 10^{-7} per year should be considered if the accident consequences may be very large. As a practical matter, scenarios with frequencies less than 10^{-7} per year will rarely need to be examined.

- ✓ Consider scenarios with frequencies of 10^{-6} to 10^{-7} per year if the consequences may be very large.
- ✓ Scenarios with frequencies less than 10^{-7} per year rarely need to be examined.
- ✓ Report the probability of the accident occurring during the lifetime of the proposed action.

In determining which low frequency accident scenarios to analyze, document preparers should consider differences between natural phenomena and human-caused events with respect to the degree to which their consideration would inform decision making. It may not be useful to consider extremely low frequency accidents resulting from certain natural phenomena. For example, in many cases the acceleration forces associated with extremely rare earthquakes (e.g., frequencies of less than 10^{-6} per year) may be so great that destructive impacts unrelated to the proposed action or alternatives would overwhelm impacts associated with the proposed action or alternatives. Such an analysis would not be informative regarding the proposed action or alternatives because a decision maker would be unable to distinguish the consequences resulting from the proposed action or alternatives from the general destructive effects of the earthquake. Analyzing a higher frequency earthquake scenario, however, could be useful in making decisions about the proposed action and alternatives, such as whether a robust earthquake design or alternative location for a proposed facility is warranted.

[5] The probability of an event occurring during a project lifetime often can be approximated by multiplying the event frequency by the project duration. This approximation method is not mathematically accurate and provides acceptable estimates only for relatively short project durations and small frequencies, as in the example above. For events with greater frequencies or longer project durations, the probability of the event taking place during the project lifetime can be calculated using the formula: Probability = $1-(1-1/T)^N$, where N = the project's lifetime in years, and T is the return period of the event in years. The annual probability of the event = 1/T. To illustrate, the probability that a 100-year storm event would occur in a given year is 0.01 [1/100]. The probability that the 100-year storm would occur during a project lifetime of 100 years is not 1.0 [100 x 0.01], rather, the probability is about 0.63 [$1-(1-1/100)^{100}$].

4.0 Risk

- ✓ Separately present estimated accident consequences and probabilities.

Presenting the risk of an accident – calculated by multiplying the probability of occurrence times the consequence – is not sufficient. As noted in *Recommendations*, presenting only the product of these two factors masks their individual magnitudes. Risk should augment and not substitute for the presentation of both the probability of occurrence and the consequence of the accident.

4.1 Application to Accidents Involving Potential Radiological Releases

- ✓ For transportation accidents, in addition to a probabilistic risk analysis, consider using a separate analysis to present both the probability and consequences of a maximum reasonably foreseeable accident.

Exposure of populations to low levels of ionizing radiation is associated with an estimated number of resulting latent cancer fatalities (LCFs) in the exposed population. If an accident involved radiation exposures, the potential LCFs would be a *consequence.*[6] The estimated number of LCFs (if the scenario were to occur) and the scenario probability should be presented in the NEPA review. This basic information may be supplemented with a risk estimate (i.e., number of LCFs multiplied by probability of the scenario).

Further, the *consequence* of a dose to an individual usually would be expressed as a *probability* that the individual would incur a fatal cancer. (This probability should not be confused with the probability that the accident scenario would occur – both should be presented in the NEPA review.) For example, for an accident that would result in a 1-rem dose to the maximally exposed member of the public, a *consequence* of the accident would be about 1 chance in 1,700 (probability of 6×10^{-4}) that the maximally exposed member of the public would incur a fatal cancer as a result of the exposure.[7]

4.2 Application to Transportation Accidents

Consistent with the emphasis in this guidance on reporting accident consequences, document preparers should consider using two separate analytical approaches for accidents involving transportation of radioactive or hazardous materials. For example, DOE often uses a probabilistic risk assessment approach for transportation accidents involving radioactive materials by summing the products of the probabilities of occurrence of accidents over a range of severity classes and the consequences of the accidents in each severity class to yield total accident risk. Although such methods typically consider the full range of potential accident severity classes, including the most severe, these methods do not present consequences for a particular accident scenario that may be of interest, such as a maximum reasonably foreseeable accident.

---

[6] Note that the numerical expression of estimated LCFs itself is probabilistic in nature and should be interpreted in a statistical sense. Nevertheless, regard the estimated number of LCFs as a *consequence* of exposure to radiation.

[7] This calculation uses a dose-to-risk conversion factor of 6×10^{-4} LCF per person-rem of exposure.

Accordingly, consider analyzing the consequences of a maximum reasonably foreseeable transportation accident using a separate approach in which a specific type of location (e.g., an urban area or a rural area) and accident scenario is postulated (typically one with an estimated occurrence of 10^{-6} to 10^{-7} per year). This approach would enable the separate presentation of both accident consequences and probability for the maximum reasonably foreseeable accident, which is often of considerable interest to the public and local officials. *A Resource Handbook on DOE Transportation Risk Assessment* (DOE, 2002b) provides useful data for transportation accident analyses.

Be sure to consider non-radiological transportation accident risks, such as fatalities from collisions that do not result in any cargo releases. In many cases, such risks will be dominant.

5.0 Accident Consequences

5.1 Involved Workers

In the analysis of accidents, always consider potential impacts on involved workers. Fatal or serious non-fatal injuries may be expected because of a worker's close proximity to the accident. In some cases, credibly estimating exposures for involved workers may require more details about an accident than could reasonably be projected or meaningfully modeled. As a substitute, the effects should be described semi-quantitatively or qualitatively, based on the likely number of people who would be involved and the general character of the accident scenario.

> **Example of a Qualitative Analysis Presentation**
>
> "Approximately 10 workers would normally be in the room where the accident could occur. While a few such workers might escape the room in time to avoid being seriously harmed, several would likely die within hours from exposure to toxic substances, and the exposed survivors might have permanent debilitating injuries, such as persistent shortness of breath."

A more detailed, semi-quantitative discussion may be appropriate for analyzing proposals with substantially greater chemical or radiological risks. Attachment 2 illustrates the application of the sliding scale principle to determining the level of detail for such analyses. It is not intended to convey all of the factors that should be considered.

5.2 Noninvolved Workers

In the analysis of accidents, always consider potential impacts on noninvolved workers.

Noninvolved workers are workers who would be on the site of the proposed action, but not involved in the action. In principle, this population consists of all workers on a DOE site that are not involved workers. In practice, to ensure that the analysis is meaningful, document preparers

should define this population and its maximally exposed member(s) in light of the specific facts and circumstances of each proposal. Attachment 2 regarding application of sliding scale principles also applies to noninvolved workers.

- ✓ Always consider impacts on involved and noninvolved workers.
- ✓ Define the noninvolved worker population and its maximally exposed member(s) for each alternative.

In many cases, a simple population impact estimate using an air dispersion model that considers the expected population between a location near the point of release (typically about 100 meters from the release point, depending on the circumstances) and the site boundary will be sufficient. In some cases, however, sub-populations of workers at the site may warrant specific consideration. Following are examples of sub-populations:

- Other workers in the same building or facility, or its immediate environs, in which an action is proposed
- Workers in buildings or locations immediately adjacent to the proposed project location (Where members of the public typically would be present in areas adjacent to noninvolved workers, such as child care centers, cafeterias or visitor centers, discuss whether accident impacts on such members of the public would be comparable to those estimated for noninvolved workers.)
- For large DOE sites with multiple facilities or geographically separate operational areas, the workers in specific downwind facilities or operational areas
- Specific classes or categories of workers that may be of special interest (See, for example, *Protection of Collocated Workers at the Department of Energy's Defense Nuclear Facilities and Sites* (DNFSB, 1999), which defines classes of populations applicable to hazardous nuclear facilities, including "collocated workers," "immediate workers," "other on-site worker personnel," "transient on-site personnel," and "off-site personnel.")

This guidance does not intend that analysis of impacts on all of these sub-populations is required, or that explicit analysis of any of the sub-populations is usually warranted in accident analyses under NEPA. Consider case-by-case, in accordance with the sliding scale principle, whether potential impacts on specific sub-populations of workers at the site and their maximally exposed members should be analyzed in light of the degree to which they may be harmed.

5.3 Accidental Contamination and Other Indirect Impacts

In evaluating the effects of an accident, characterize the degree to which buildings, land, and environmental media would be contaminated, and describe (at least qualitatively) the potential health and environmental effects from such contamination, including direct and indirect effects associated with potential cleanup activities. To the extent that such effects are not remote and speculative, and as appropriate in accordance with a sliding scale approach, consider the

potential for other indirect effects of accidents (e.g., lasting economic effects, such as potential impacts on a commercial fishery or the costs of cleanup).

5.4 Radiological Ecological Impacts

Potential impacts to biota should be evaluated, as appropriate, when analyzing radiological accident scenarios under NEPA.

An adequate analysis of potential impacts on people from accidents can serve as a relative basis for analyzing impacts on biota in many cases, particularly when analysis shows that people likely would not be harmed. Although recent reports suggest there may be exceptions, in general, radiological doses that are unlikely to affect humans (e.g., doses below human radiation protection limits) are not known to cause measurable adverse effects to populations of plants and animals. This assumption may require further consideration in cases where human access to a contaminated area is restricted but access by other biota is not, unique exposure pathways exist for plants and animals that do not affect exposure of humans, and other stresses on plants and animals are significant (IAEA, 1992; ORNL, 1995).

- ✓ Analyze impacts to biota, as appropriate, when analyzing radiological accident scenarios under NEPA.
- ✓ An analysis of impacts to people often can be the basis for conclusions regarding impacts to biota.
- ✓ It is usually sufficient to consider accident impacts on plant and animal populations rather than on individuals.

Regarding the current state of the science on dose limits for protection of biota, the International Atomic Energy Agency (IAEA), Technical Report Series No. 332, *Effects of Ionizing Radiation on Plants and Animals at Levels Implied by Current Radiation Protection Standards, 1992*, states that "[a]cute doses of 0.1 Gy [10 rad] or less are very unlikely to produce persistent, measurable deleterious changes in populations or communities of terrestrial plants or animals." For chronic exposures, the IAEA concludes that "[t]here is no convincing evidence from the scientific literature that chronic radiation dose rates below 1 mGy/d [0.1 rad/day] will harm animal or plant populations." Additionally, for the aquatic environment, the National Council on Radiation Protection (NCRP) concluded that a chronic dose of less than 10 mGy/d [1 rad/day] to the maximally exposed individual in a population of aquatic organisms would ensure protection of the population (NCRP, 1991).The IAEA is continuing to review and discuss concepts for a radiological protection framework for the environment, to include appropriate effects levels and dose limits for biota (IAEA, 1999; IAEA, 2002).

In analyzing accidents under NEPA, it is sufficient to consider only effects on flora and fauna populations, rather than individual members of a species, except in rare cases where (1) endangered or threatened species may be affected, or (2) commercially or culturally-valued species may be affected.

If no ecological effects from exposure to ionizing radiation would be expected, make a negative declaration, accompanied by a brief explanation of the scientific methodology and sources (such

as the 1992 IAEA report) relied upon in arriving at conclusions regarding impacts (40 CFR 1502.24).

- ✓ Explain the nature and relevance of uncertainties in presenting the results of accident analyses.
- ✓ Describe the effect of incomplete or unavailable information on the results of accident analyses.

The Office of Environmental Policy and Guidance, through the Department's Biota Dose Assessment Committee (BDAC), has developed a DOE Technical Standard, "A Graded Approach for Evaluating Radiation Doses to Aquatic and Terrestrial Biota" (DOE, 2000). The methodology, which uses assumptions of equilibrium conditions, is not intended for short-term, acute exposures that might be experienced during an accident. However, the methodology can be used to provide an indication of long-term recovery or health of a population following an accident. A summary of DOE's existing and recommended dose limits for protection of biota, and their technical basis, is also provided. A copy of the document may be downloaded from the DOE Technical Standards Program Web Site at: http://tis.eh.doe.gov/techstds/tsdrafts/envr0011 and from the BDAC Web Site at: http://homer.ornl.gov/oepa/public/bdac.

5.5 Non-radiological Ecological Effects

- ✓ Consider non-radiological chemical and physical effects on biota commensurate with significance.

In considering potential non-radiological effects on biota, take account of differences among receptors with respect to sensitivity to toxic chemicals and routes of exposure. Accidents that do not result in immediate harm to humans could substantially harm biota (e.g., liquid chemical spills that result in fish kills).

6.0 Uncertainty

Many factors may contribute to uncertainty in accident analyses under NEPA. For example, NEPA documents often are prepared at the conceptual design phase of proposed new facilities, when design details are not available, resulting in uncertainties regarding accident scenarios.

- ✓ Provide references for key data and assumptions used in accident analyses.

Decision makers need to understand the nature and extent of uncertainty in choosing among alternatives and considering potential mitigation measures. In all cases, the NEPA document should explain the nature and relevance of the uncertainty. Where uncertainties preclude quantitative analysis, the unavailability of relevant information should be explicitly acknowledged. The NEPA document should describe the analysis that is used, and the effect the incomplete or unavailable information has on the ability to estimate the probabilities or consequences of reasonably foreseeable accidents (40 CFR 1502.22).

In circumstances where substantial uncertainty exists regarding the validity of estimates, a qualitative estimate may be used. Regardless of whether a qualitative or quantitative analysis is performed, references supporting scenario probabilities, release fractions, and other data and assumptions used in the accident analysis should be provided.

Avoid presenting estimates for uncertain parameters that are unjustifiably precise (such as two significant figures for probability estimates). NEPA documents often are prepared before the detailed designs that would be needed for more precise estimates are available. Further, as described in *Recommendations*, for events that have large consequences, use a range of probabilities rather than a single estimate if it is not possible to determine the probability with much certainty. For events whose consequences are relatively low and numerical probability estimates are unavailable or difficult to obtain, qualitative descriptions such as “very infrequent” or “highly unlikely” may be adequate if the basis for such conclusion is provided.

7.0 Information Sources

Existing documents supporting the integrated safety management system (ISMS) for a facility or operation are potentially valuable sources of information for accident analyses under NEPA. Using these documents may help streamline the NEPA process by avoiding the duplication of analysis, and foster consistency in the Department’s analyses. Further, their use can help ensure that the NEPA document benefits from the rigor required by the ISMS process.

This guidance refers generally to safety documents as *authorization basis* documents to emphasize their purpose as part of the process for authorizing nuclear or non-nuclear operations. These documents can include safety analysis reports, safety assessment documents, and several other commonly used formats. For nuclear facilities, most, if not all, authorization basis documents will be part of the documented safety analysis (DSA), which documents the extent to which a nuclear facility can be operated safely with respect to workers, the public, and the environment, including a description of the conditions, safe boundaries, and hazard controls that provide the basis for ensuring safety (10 CFR 830.3). Authorization basis documents may also include documents prepared in support of the ISMS process for non-nuclear facilities and operations.

- ✓ In many cases, existing authorization basis documents may be summarized and incorporated by reference in NEPA accident analyses.
- ✓ Additional analyses may be required to consider beyond-design-basis accidents, worker impacts, or new hazards.
- ✓ Make sure that assumptions in authorization basis documents are appropriate for the NEPA review.
- ✓ Ensure that accident risk comparisons among alternatives are fair by using a consistent set of assumptions or clearly noting any differences.

NEPA document preparers will need to review authorization basis documents to determine whether the major assumptions and scenarios are

valid and appropriate for use in NEPA accident analyses. In conducting such reviews, NEPA document preparers should understand the different purposes of authorization basis and NEPA documents. For example, one purpose of a DSA and its accompanying hazard controls is to provide reasonable assurance that a DOE nuclear facility can be operated safely by defining and controlling commitments for design, procurement, construction, and operation. To accomplish that purpose, the DSA and accompanying hazard controls require substantially greater details of design and specific operations than are usually available when NEPA documents are prepared. NEPA documents usually are prepared early in the life cycle of proposed facilities, when only conceptual design information is available, and usually would precede authorization basis documents.

Authorization basis documents may be relevant for NEPA documents in several circumstances. For example, a NEPA document may consider a proposal to conduct a certain activity at an existing facility for which an authorization basis document exists. The existing facility may or may not require substantial improvements to enable the new activity, and the authorization basis document may or may not have explicitly considered the proposed new activity (e.g., prior to a decision whether to proceed with the proposal, regular updates to a DSA may not incorporate the proposed action).

If the major assumptions in the authorization basis document would remain valid for the proposed new activity then the accident analysis for the NEPA document may require no more than that the authorization basis document be summarized and incorporated by reference (40 CFR 1502.21). Even if the NEPA document requires further information to supplement analysis in the authorization basis document (e.g., to consider reasonably foreseeable beyond design basis accidents,[8] impacts to workers, or specific analysis of a new hazard), using information from the authorization basis document could improve the efficiency of the NEPA document preparation process.

In the example above, the NEPA document would analyze reasonable alternatives to locating a proposed activity at an existing facility, such as the construction of a new facility. Detailed design information would not be available for the proposed new facility, however, and an accident analysis for the new facility would need to be based on conceptual design. This poses a concern that comparisons of the accident risks among the alternatives would not be fair. For example, documentation for the existing facility might justify use of assumptions or analyses that take credit for a substantially greater degree of containment of accidental releases than might be

[8] "Design basis accidents" are accidents that are postulated for the purpose of establishing functional requirements for safety class and safety significant structures, systems, components, and equipment. A "beyond design basis accident" is an accident of the same type as a design basis accident (e.g., fire, earthquake, spill, explosion, etc.), but defined by parameters that exceed in severity the parameters defined for the design basis accident (DOE 2002a). In safety analysis reports, DOE considers the likelihood and consequences of beyond design basis accidents to provide a complete and documented rationale for acceptance or rejection of the operation of a facility, and to estimate the residual risk associated with facility accidents. Not all authorization basis documents have analyzed beyond design basis accidents. (Under NEPA, reasonably foreseeable accidents may or may not include both "design basis" and "beyond design basis" accidents, as described in the authorization basis documents.

justified for a new facility. An accident analysis could be misleading if it presented greater accident risks for the new facility without explaining the different assumptions used.

To ensure that accident risk comparisons among alternatives are fair, preparers should note differences in the analytical approaches used in the information sources for accident analyses, such as differences in the degree of conservatism and analytical approach (e.g., some NEPA and authorization basis documents have used different assumptions for meteorological conditions, dose commitment and accumulation duration, and other parameters). Preparers should ensure that all of the analyses are based on a consistent set of assumptions, or that differences are clearly explained.

In reviewing authorization basis documents for potential use as information sources in NEPA documents, consider whether accidents beyond the facility's design basis should be included in the NEPA document. If so, and if the authorization basis document did not consider beyond design basis accidents, then additional analysis will be required for NEPA compliance.

Because NEPA documents for new facilities are often prepared during the conceptual planning phase of a proposed project (and before start of detailed title II design), authorization basis documentation is usually not available to support the NEPA review. In some cases draft or preliminary authorization basis documents are available and may be a valuable source of information. For example, a preliminary documented safety analysis (PDSA) is prepared at an early stage in a nuclear facility's life cycle, when approval is sought for design, procurement, and construction. PDSAs are developed based on preliminary information regarding design and operating procedures. Although their purpose (to demonstrate that safe operation is possible and that design and operational constraints have been considered) differs from the purpose of a NEPA document, it may be possible to integrate their preparation with the NEPA process. Integrating a NEPA accident analysis with the corresponding authorization basis document preparation process would be highly desirable, although it will not always be possible to do.

As with any non-classified reference used to support a NEPA review, if a draft or preliminary authorization basis document is referenced in a NEPA accident analysis, then the referenced document (or the relevant parts thereof) must be available to the public.

8.0 References

DNFSB 1999, Protection of Collocated Workers at the Department of Energy's Defense Nuclear Facilities and Sites, Report No. DNFSB/TECH-20, Defense Nuclear Facilities Safety Board, Washington, DC, February.

DOE 1993, Recommendations for the Preparation of Environmental Assessments and Environmental Impact Statements, Office of NEPA Oversight, U.S. Department of Energy, Washington, DC, May.

DOE 2000, DOE Draft Technical Standard, A Graded Approach for Evaluating Radiation Doses to Aquatic and Terrestrial Biota, Office of Environmental Policy and Guidance, U.S. Department of Energy, Washington, DC, June.

DOE 2002a, DOE Technical Standard, DOE-STD-3009-94, Change Notice 2, Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Documented Safety Analyses, U.S. Department of Energy, Washington, DC.

DOE 2002b, A Resource Handbook on DOE Transportation Risk Assessment, DOE Transportation Risk Assessment Working Group Technical Subcommittee, National Transportation Program, U.S. Department of Energy, Albuquerque, NM.

EPA 1999, Cancer Risk Coefficients and Environmental Exposure to Radionuclides, Federal Guidance Report No. 13, Eckerman, K.F., R.W. Leggett, C.B. Nelson, J.S. Puskin, and A.C.B. Richardson, U.S. Environmental Protection Agency, Washington, DC.

IAEA 1992, Effects of Ionizing Radiation on Plants and Animals at Levels Implied by Current Radiation Protection Standards. Technical Report Series No. 332, International Atomic Energy Agency, Vienna, Austria.

IAEA 1999, Protection of the Environment from the Effects of Ionizing Radiation: A Report for Discussion. IAEA-TECDOC-1091, International Atomic Energy Agency, Vienna, Austria.

IAEA 2002, Ethical Considerations in Protecting the Environment from the Effects of Ionizing Radiation: A Report for Discussion, IAEA-TECDOC-1270, International Atomic Energy Agency, Vienna, Austria.

NCRP 1991, Effects of Ionizing Radiation on Aquatic Organisms. NCRP Report No. 109, National Council on Radiation Protection and Measurements. Bethesda, MD.

NRC 1983, Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants. Revision 1. Regulatory Guide 1.145. U.S. Nuclear Regulatory Commission, Washington, DC.

NRC 1993, Health Effects Models for Nuclear Power Plant Accident Consequence Analysis, Report No. NUREG/CR-4214, Rev. 2, Part I, Evans, J.S., S. Abrahamson, M.A. Bender, B.B. Boecker, E.S. Gilbert, and R.R. Scott, U.S. Nuclear Regulatory Commission, Washington, DC.

ORNL 1995. Effects of Ionizing Radiation on Terrestrial Plants and Animals: A Workshop Report, Report No. ORNL/TM-13141, Barnthouse, L.W., Oak Ridge National Laboratory, Oak Ridge, Tennessee.

Regulations:

40 CFR Parts 1500-1508, Council on Environmental Quality, Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act.

10 CFR Part 830, Department of Energy, Nuclear Safety Management.

Related Issue: Intentional Destructive Acts (i.e., Acts of Sabotage or Terrorism)

In identifying the reasonably foreseeable impacts of a proposed action and alternatives, past DOE NEPA documents have addressed potential environmental impacts that could result from intentional destructive acts. Analysis of such acts poses a challenge because the potential number of scenarios is limitless and the likelihood of attack is unknowable.

Intentional destructive acts are not accidents. Nevertheless, NEPA documents have stated that the physical effects of a destructive act – whether caused by a fire, explosion, missile or other impact force – may be compared with the effects of accidents. That is, the consequences of an act of sabotage or terrorism could be discussed by a comparison to the consequences of a severe accident because the forces that could result in a release of radioactive or hazardous material would be similar to those considered in accident analyses. In some cases where the Department has considered destructive acts in a NEPA document, including facility and transportation scenarios, the consequences of destructive acts were "bounded" by those of severe accidents analyzed in the document. In other cases, the consequences of the destructive act were greater than but similar to those of accidents analyzed in the document.

When intentional destructive acts are reasonably foreseeable, a qualitative or semi-quantitative discussion of the potential consequences of intentional destructive acts could be included in the accident analyses.

Following are two examples of qualitative discussions of intentional destructive acts that might be appropriate in an EIS. The first example discusses potential sabotage at a hypothetical proposed fixed facility at a DOE site. This discussion might be appropriate for a proposal at the low-to-middle range of the sliding scale. The second example integrates a discussion of sabotage into a summary of accident impacts for a hypothetical proposal involving the transportation of nuclear waste or spent nuclear fuel. This discussion might be appropriate for a proposal at the high-end of the sliding scale.

Example of a Qualitative Discussion of Potential Sabotage on a Proposed Fixed Facility ("low" to "middle" sliding scale proposal)

In the aftermath of the tragic events of September 11, 2001, DOE is continuing to consider measures to minimize the risk and consequences of a potential terrorist attack. The proposed facility would offer certain unique features from a safeguards perspective: a remote location, restricted access afforded by Federal land ownership, restricted airspace above the site, and access to a highly effective rapid-response security force.

DOE based its analysis of the proposed facility on conceptual design information. If DOE decides to construct and operate the facility, as part of its detailed design and planning

processes, DOE would continue to identify safeguards, security measures, and design features that would further protect the facility from terrorist attack and other forms of sabotage. DOE believes that the safeguards applied to the proposed facility should involve a dynamic process of enhancement to meet threats, which could change over time. Potential additional measures that DOE could adopt include:

- Facilities with thicker reinforced walls and roofs designed to mitigate the potential consequences of the impact of airborne objects
- Underground or surface bermed structures to lessen the severity of damage from aircraft crashes
- Additional doors, airlocks, and other features to delay unauthorized intrusion
- Additional site perimeter barriers
- Active denial systems to disable any adversaries and prevent access to the facility.

Although it is not possible to predict if sabotage events would occur, and the nature of such events if they did occur, DOE examined several accident scenarios that approximate the types of consequences that could occur. These accidents and their consequences are discussed in Section X.Y.Z.

Example of a Summary Discussion of Transportation-Related Accidents and Sabotage ("High" Sliding Scale Proposal)

In the EIS analysis DOE considered potential accidents based on the 19 truck and 21 rail accident cases presented in NUREG-6672, *Reexamination of Spent Fuel Shipment Risk Estimates* (issued in March 2000). DOE estimated potential impacts of postulated releases from accidents in three population zones – urban, suburban, and rural – under a set of meteorological (weather) conditions that represent the national average meteorology. In estimating accident probabilities, DOE used state-specific accident data, the lengths of routes in the population zones in states through which the shipments would pass, and the number of shipments. DOE also considered the risk of accidents involving both releases of radioactive material and loss-of-shielding accidents.

DOE also estimated impacts from unlikely but severe accidents called *maximum reasonably foreseeable accidents* to provide perspective about the consequences for a population that might live nearby. In its analysis of maximum reasonably foreseeable accidents, DOE considered each of the accidents presented in NUREG-6672 for both truck and rail transportation. For each accident, the possible combinations of weather conditions, population zones, and transportation modes were considered. The accidents

were then ranked according to those that would have a likelihood greater than one in 10 million per year (accidents that DOE regards as reasonably foreseeable) and that would have the greatest consequences.

Real life transportation accidents involve collisions of many kinds, such as with other vehicles and along-the-route obstacles, involvement in fires and explosions, inundation, and burial. These accidents are caused, in turn, by a variety of initiating events including human error, mechanical failure, and natural causes such as earthquakes. Accidents occur in many different kinds of places including mountain passes and urban areas, rural freeways in open landscapes, and rail switching yards.

Thus, there are as many different kinds of unique initiating events and accident conditions as there are accidents. Analyzing each accident that could occur would not be practical. However, it is practical to analyze a limited number of accidents, each of which represents a grouping of initiating events and conditions having similar characteristics and encompassing a reasonable range of accidents. For example, the EIS analyzes the impacts of a collection of collision accidents in which a cask would be exposed to impact velocities in the range of 60 to 90 miles (97 to 145 kilometers) per hour. The EIS also analyzes a maximum reasonably foreseeable accident in which a collision would not occur but where the temperature of a rail cask containing spent nuclear fuel would rise to between 1,400^{o}F and 1,800^{o}F (between 750^{o}C and 1,000^{o}C). The conditions of the maximum reasonably foreseeable accident analyzed in the EIS envelope conditions reported for the Baltimore Tunnel fire (a train derailment and fire that occurred in July 2001 in Baltimore, Maryland). Temperatures in that fire were reported to be as high as 1,500^{o}F (820^{o}C), and the fire was reported to have burned for up to five days.

The estimated consequences of the maximum reasonably foreseeable transportation accident (an accident with the highest consequence for human health that can be reasonably foreseen) would be higher for rail transportation (five LCFs) than for truck shipments (one LCF), principally because the amount of material in a rail shipment would be larger than that in a truck shipment.

DOE also evaluated the potential consequences of an accidental crash of a large jet aircraft into a truck cask or rail cask. The analysis determined that penetration of the cask would not occur; however, potential seal failure could result in releases of radiological materials. The consequences associated with this event would be less than one latent cancer fatality (LCF) in an urban population.

The proposed action includes physical safeguards aimed at protecting the public from harm that could result from sabotage. Such safeguards would minimize the possibility of sabotage and facilitate the recovery of spent nuclear fuel shipments that could come under control of unauthorized persons. Safety features of transportation casks that provide containment, shielding and thermal protection also provide protection against sabotage. The casks would be massive.

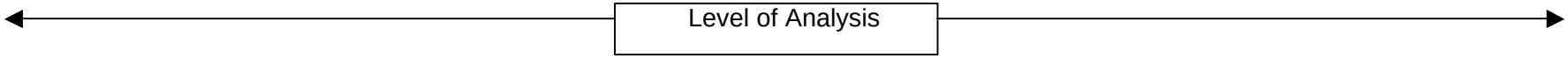
It is not possible to predict whether sabotage events would occur and, if they did, the nature of such events. Nevertheless, DOE examined various accidents, including an aircraft crash into a transportation cask. The consequences of both the maximum reasonably foreseeable accident and the aircraft crash are presented in Section X.X.X for both rail and truck transportation, and provide an approximation of the type of consequences that could occur from a sabotage event. In addition, DOE estimated the potential consequences of a saboteur using a device to attack a truck or rail cask. Using highly-conservative assumptions, this analysis indicates that such an event could result in approximately 50 latent cancer fatalities in an assumed population of a large urban area.

DOE continues to examine the protections built into its physical security and safeguards systems for transportation shipments. DOE would modify its methods and systems as appropriate based on the results of this examination.

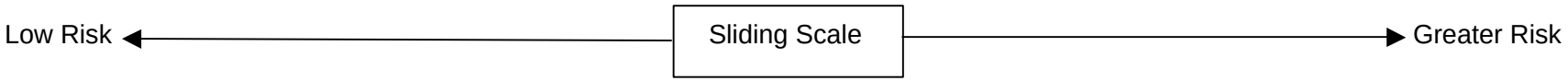
Attachment 2

Illustration:

Application of Sliding Scale Concepts to the Analysis of Potential Impacts on Workers from a Chemical Release Accident



Qualitative	Semi-Quantitative	Quantitative
Narrative discussion of potential consequences • Estimated number of workers at risk • Summary of potential acute and chronic consequences • Detailed discussion of engineering controls or other potential mitigation measures usually unwarranted	Gross estimates of chemical concentrations at receptor location(s) Comparison of chemical concentrations to appropriate health-related references, such as: • Emergency Response Planning Guidelines (ERPGs) • Temporary Emergency Exposure Limits (TEELs) • Reference Concentrations (R_fCs) Simplistic exposure assumptions (e.g., assume 15-minute time-weighted average for events with long release periods unless there are counter indications, such as substances that cause immediate adverse effects)	In addition to semi-quantitative considerations: Explicit consideration of mitigation measures, such as engineering controls, inventory reduction, and design changes Detailed dispersion modeling (e.g., time profile and frequency distribution of releases and concentrations at receptor locations) Potential for physical or chemical form changes (e.g., phosgene formation from carbon tetrachloride combustion; liquid-to-vapor changes) Detailed health effects analysis (e.g., potential impairment effects, dose-dependent effects, combined effects)



Attachment 3

Reprinted from *Recommendations for the Preparation of Environmental Assessments and Environmental Impact Statements*, May 1993 (“Green Book”)

6.4 ACCIDENT ANALYSIS

Background

This section deals with environmental impacts that will not necessarily occur under a proposed action, but which are reasonably foreseeable. The term "reasonably foreseeable" has no precise definition. Its interpretation should be guided by two primary purposes of NEPA review: (1) to determine whether a proposed action has the potential for significant impacts (EA), and (2) to inform an agency (and the public) in making reasonable choices among alternatives (EA and EIS).

For both purposes above, "reasonably foreseeable" includes impacts that may have very large or catastrophic consequences, even if their probability of occurrence is low, provided that the impact analysis is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason. Note, however, that a high-consequence event would not necessarily have "significant impacts" (in the sense of NEPA) if its probability of occurrence is very low. (The probability referred to in these discussions is the probability of the consequences of the accident or failure scenario occurring, not the probability of the initiating event occurring.)

EAs normally deal with proposed actions and analyzed alternatives that would not have potential for significant adverse impacts even under accident conditions. In contrast, EISs normally deal with larger scale projects that may have such potential. As with the choice of alternatives and the analysis of environmental impacts, use a sliding scale approach in considering impacts from potential accidents (or abnormal events). The nature of the proposed action or analyzed alternatives determines what types of potential accidents to consider, whether to describe impacts from accidents qualitatively or to analyze them quantitatively, and to what extent to consider very low probability events. Analyze impacts from reasonably foreseeable accidents to about the same extent as other impacts from the proposed action or analyzed alternatives, or even to a greater extent where impacts from accidents are the dominant concern.

Recommendations: Steps for determining which accident scenarios to analyze

- Identify the spectrum of potential accident scenarios (e.g., fire, impact or puncture events, HEPA filter failure) that could occur during construction, operations, and transportation activities encompassed by the proposed action and analyzed alternatives. Also identify failure scenarios from natural events (e.g., tornadoes, earthquakes) and human error (e.g., forklift accidents).

  For a proposed action that involves a facility or component with a set of design basis

criteria (DOE 6430.1A[9]), consider the following two major categories of accidents.

Within design basis: First focus on accident, failure, or error scenarios within the design basis and determine the type of event that is likely to cause the greatest consequences, supporting that determination with rough estimates of or qualitative judgments about the magnitude of the consequences. Typically, these events will have probabilities of greater than 10^{-6} per year, especially for natural phenomenon events.

Beyond design basis: Look beyond design basis to see if there may be events of such large consequences that they need to be considered in order to satisfy the primary purposes of NEPA review as stated in the first paragraph in this section. Generally, examine the probability range 10^{-6} to 10^{-7} per year to the degree that events within this range bear on satisfying the two primary purposes of NEPA review cited above. As a practical matter (including litigation history), events with probabilities less than 10^{-7} per year will rarely need to be examined.

- Describe events that have very small consequences only qualitatively in the NEPA review, regardless of the probabilities.
- For events whose consequences are relatively low and numerical probability estimates are unavailable or difficult to obtain, qualitative descriptions such as "very infrequent" or "highly unlikely" may be used, provided that the basis for such a conclusion is described.
- Analyze events that have large consequences in terms of both their probabilities and consequences. If it is not possible to determine the probability with much certainty, use a range of probabilities.
- The term "consequence" refers to the results of an accident without consideration of the probability of the accident. Often, the product of probability and consequence, referred to as "risk," is provided as a measure of impact, but this product is not as informative as a presentation of its separate factors and is not the only definition of "risk."

Recommendations: Factors to consider in accident impact analysis

- Consider impacts on the public and on workers.
- Consider synergistic effects with nearby facilities, chemical as well as radiological.
- Consider common mode failures, including external initiators (such as earthquakes).
- Reference Safety Assessments and Safety Analysis Reports, if available.

[9] Since *Recommendations* was issued, DOE Order 6430.1A was replaced with two performance-based Orders: DOE O 420.1A, FACILITY SAFETY, and DOE O 430.1A, LIFE CYCLE ASSET MANAGEMENT. In addition, there are Guides and other documents developed for use with DOE O 420.1A and DOE O 430.1A which provide acceptable methodologies for satisfying requirements, including guidance on selecting industry codes and standards for aspects of design.

EXHIBIT 9

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Effective June 24, 1994, Published in Federal Register, July 5, 1994 (59 FR 34496)
Amendment Effective July 28, 1994, Federal Register, August 5, 1994 (59 FR 40170)
Amendment Effective April 17, 1995, Federal Register, April 27, 1995 (60 FR 20726)
Amendment Effective December 14, 1995, Federal Register, January 19, 1996 (61 FR 1482)
Amendment Effective March 1, 1996, Federal Register, March 12, 1996 (61 FR 10004)
Amendment Effective January 23, 1997, Federal Register, January 31, 1997 (62 FR 4782)
Amendment Effective September 30, 1997, Federal Register, October 14, 1997 (62 FR 53335)
Amendment Effective October 20, 1997, Federal Register, October 29, 1997 (62 FR 56196)
Amendment Effective October 22, 1997, Federal Register, October 31, 1997 (62 FR 59032)
Amendment Effective February 4, 1998, Federal Register, February 17, 1998 (63 FR 8052)
Amendment Effective April 30, 1998, Federal Register, May 11, 1998 (63 FR 26018)
Amendment Effective April 29, 1999, Federal Register, May 11, 1999 (64 FR 25361)
Amendment Effective October 2, 2000, Federal Register, October 10, 2000 (65 FR 60328)
Amendment Effective December 28, 2000 Federal Register, January 5, 2001 (66 FR 1146)
Amendment Effective December 11, 2001 Federal Register, December 11, 2001 (66 FR 64051)
Amendment Effective December 19, 2001 Federal Register, November 19, 2001 (66 FR 57970)
Amendment Effective January 10, 2002 Federal Register, December 11, 2001 (66 FR 64052)
Amendment Effective January 24, 2002 Federal Register, November 19, 2001 (66 FR 57970)

NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (NIH GUIDELINES)

April 2002

****

Visit the OBA Web site at:
http://www4.od.nih.gov/oba
For current information on Guidelines, Protocols, Principal Investigators, Meetings, and information about upcoming Gene Therapy Policy Conferences

****

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

These *NIH Guidelines* supersede all earlier versions and shall be in effect until further notice.

****

TABLE OF CONTENTS

In constructing the *NIH Guidelines*, it was necessary to define boundary conditions for the different levels of physical and biological containment and for the classes of experiments to which they apply. These definitions do not take into account all existing and anticipated information on special procedures that will allow particular experiments to be conducted under different conditions than indicated here without affecting risk. Individual investigators and Institutional Biosafety Committees are urged to devise simple and more effective containment procedures and to submit recommended changes in the *NIH Guidelines* to permit the use of these procedures.

****

SECTION III. EXPERIMENTS COVERED BY THE *NIH GUIDELINES*

This section describes six categories of experiments involving recombinant DNA: (i) those that require Institutional Biosafety Committee (IBC) approval, RAC review, and NIH Director approval before initiation (see Section III-A), (ii) those that require NIH/OBA and Institutional Biosafety Committee approval before initiation (see Section III-B), (iii) those that require Institutional Biosafety Committee and Institutional Review Board approvals and RAC review before research participant enrollment (see Section III-C), (iv) those that require Institutional Biosafety Committee approval before initiation (see Section III-D), (v) those that require Institutional Biosafety Committee notification simultaneous with initiation (see Section III-E), and (vi) those that are exempt from the *NIH Guidelines* (see Section III-F).

Note: *If an experiment falls into Sections III-A, III-B, or III-C and one of the other sections, the rules pertaining to Sections III-A, III-B, or III-C shall be followed.* If an experiment falls into Section III-F and into either Sections III-D or III-E as well, the experiment is considered exempt from the *NIH Guidelines*.

Any change in containment level, which is different from those specified in the *NIH Guidelines*, may not be initiated without the express approval of NIH/OBA (see Section IV-C-1-b-(2) and its subsections, *Minor Actions*).

Section III-A. Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation (See Section IV-C-1-b-(1), Major Actions).

Section III-A-1. Major Actions under the *NIH Guidelines*

Experiments considered as *Major Actions* under the *NIH Guidelines* cannot be initiated without submission of relevant information on the proposed experiment to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax), the publication of the proposal in the *Federal Register* for 15 days of comment, review by RAC, and specific approval by NIH. The containment conditions or stipulation requirements for such experiments will be recommended by RAC and set by NIH at the time of approval. Such experiments require Institutional Biosafety Committee approval before initiation. Specific experiments already approved are included in Appendix D, *Major Actions Taken under the NIH Guidelines*, which may be obtained from the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

Section III-A-1-a. The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see Section V-B, *Footnotes and References of Sections I-IV*), if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by RAC.

Section III-B. Experiments That Require NIH/OBA and Institutional Biosafety Committee Approval Before Initiation

Experiments in this category cannot be initiated without submission of relevant information on the proposed experiment to NIH/OBA. The containment conditions for such experiments will be determined by NIH/OBA in consultation with *ad hoc* experts. Such experiments require Institutional Biosafety Committee approval before initiation (see Section IV-B-2-b-(1), *Institutional Biosafety Committee*).

EXHIBIT 10

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

JOSEPH P. RUSSONIELLO
United States Attorney
CHARLES O'CONNOR
Assistant United States Attorney
450 Golden Gate Ave., Box 36055
San Francisco, CA 94102
Telephone: (415) 536-6967
Facsimile: (415) 436-6748

RONALD J. TENPAS
Assistant Attorney General
BARCLAY T. SAMFORD (NMBN 12323)
Trial Attorney
U.S. Department of Justice
Environment & Natural Resources Div.
1961 Stout St., 8th Floor
Denver, CO 80294
Telephone: (303) 844-1475
Facsimile: (303) 844-1350

Attorneys for Defendants

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

TRI-VALLEY CARES, MARYLIA KELLEY, JANIS KATE TURNER, and JEDIDJAH DE VRIES Plaintiffs, v. UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION, LAWRENCE LIVERMORE NATIONAL LABORATORY, Defendants.	Case No. 08-cv-1372-SBA DECLARATION OF JEFFREY STIEFEL

I, Jeffrey Stiefel, hereby declare and state as follows:

1. I am the Director for the Early Detection Division within the Office or Heal h Affairs at the Department of Homeland Security (DHS). I have been employed by DHS since Jul 2004. The Early Detection Division is responsible for oversight of the national BioWatch Prog am with monitors the air for the intentional release of a bioterrorist agent on a daily bases in greater than 30 Jurisdictions across the country. I have a Ph.D. in Biology/Molecular Genetics and over 30 years experience as a technical program manager. I also worked at the U.S. Army Medic l Research Institute for Infectious Diseases located at Ft. Detrick, MD in their high containmen BSL-3 facility for 5 years.

2. The Purpose of this declaration is to describe the importance of continuing perations at the Lawrence Livermore National Laboratory (LLNL) Bio-safety Level 3 (BSL-3) faci ity and some of the adverse impacts that would result if operations at the facility were delayed by an injunction.

3. DHS' BioWatch program involves the collection and analysis of air sample s from key urban areas across the country for the purpose of detecting a potential release of a terroris -related biological agent. As part of this program, key laboratories perform screening analyses using DNA extract identification method called Polymerase Chain Reaction (PCR) analysis. When a s creening analysis identifies a threat biological agent, a confirmatory analysis must be performed. Th procedure for such an analysis uses culturing, which involves growing the organism from the pos tive sample to determine whether it is alive and therefore poses a public health threat. In addition the sample could be used by law enforcement for forensics in trying to establish the origin of the ag nt. Depending upon the agent, growing a biological organism with these characteristics might be erformed in a BSL-3 approved facility.

4. Under the national BioWatch program, the Centers for Disease Control an Prevention have the lead role in performing characterization testing, and LLNL is tasked to provide backup laboratory and characterization testing. Without LLNL's BSL-3 facility, characterization test ng to include "culturing" cannot be submitted to LLNL. The lack of an adequate backup facility can cause, and has caused, delays in characterization testing. In one instance, the necessary CDC lab ratory was out of operation for a period of time, and characterization testing had to be delayed by ap roximately four days until the laboratory was again available for use. Without the addition of the LLNL BSL-3 level laboratory, there is the potential to significantly delay the scientific scrutiny of the identified agent that could impact response and mitigation to a bioterriorism event. For example, t e ability to test for antibiotic susceptibility which could lead to additional deaths by not providing ap ropriate thereputics.

5. The lack of the BSL-3 level laboratory at LLNL would also limit DHS' a ility to provide comprehensive bioforensics analysis. Currently, the LLNL provides DHS with a obust bioforensics capability at the BSL-2 level. However, DHS law enforcement and intelligence-r lated activities sometimes require a BSL-3 capability. For example, it is important for the United States to be able to determine who might be responsible for manufacturing specific biological materi l by understanding the specific properties/characteristics associated with the confiscated material. Th se are known as attribution studies.

6. For these reasons, it is my professional opinion that LLNL's BSL-3 facili y significantly improves our Nation's ability to detect and respond to the threat of terrorism usin biological agents, and that halting operations at LLNL's BSL-3 facility would directly impact the n tional security of the United States.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Signed this 26 day of March, 2008.

Jeffrey Stiefel

EXHIBIT 11

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

JOSEPH P. RUSSONIELLO
United States Attorney
CHARLES O'CONNOR
Assistant United States Attorney
450 Golden Gate Ave., Box 36055
San Francisco, CA 94102
Telephone: (415) 536-6967
Facsimile: (415) 436-6748

RONALD J. TENPAS
Assistant Attorney General
BARCLAY T. SAMFORD (NMBN 12323)
Trial Attorney
U.S. Department of Justice
Environment & Natural Resources Div.
1961 Stout St., 8th Floor
Denver, CO 80294
Telephone: (303) 844-1475
Facsimile: (303) 844-1350

Attorneys for Defendants

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

TRI-VALLEY CARES, MARYLIA KELLEY, JANIS KATE TURNER, and JEDIDJAH DE VRIES Plaintiffs, v. UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION, LAWRENCE LIVERMORE NATIONAL LABORATORY, Defendants.	Case No. 08-cv-1372-SBA DECLARATION OF SUSAN ELIZABETH GEORGE

I, Susan Elizabeth George, hereby declare and state as follows:

1. I am the Division Head of the Chemical and Biological Division (CBD) within the Science and Technology directorate at the Department of Homeland Security (DHS). I have held this position since March 2008. For the past 5 years, I have been the Deputy for the program. CBD is an Research and Development (R&D) chemical and biological countermeasures program that addresses threat awareness, support for attribution, surveillance and detection, restoration and agrodefense.

2. CBD has an active R&D program in biological surveillance and detection which will require BSL-3 capability to better understand the potential influence of virulence, viability, and countermeasures resistance markers in the near term and those of the advanced threat in the far term. The resulting high impact markers will be developed into next generation detection systems. Lawrence Livennore National Laboratory (LLNL) is one of three DOE national laboratories that has self identified as a CBD provider through the Under Secretary's process.

3. By using the LLNL BSL-3 capability, the DHS will have both convenience and flexibility. DHS projects will have access to this limited capability as well as the security of engaging with a provider that has already negotiated a contract that protects United States government interests (e.g. security, protection of Intellectual Property). Therefore, the United States government will have the ability to hold signatures and assays closely through this mechanism, thus making it in the interest of national security. In addition, DHS will not need to negotiate a new contract for these benefits, to include infrastructure costs, thus saving time and money.

4. In the event of a biological attack, on demand BSL-3 surge capability may be needed for operational bioforensics applications. Even though the National Biodefense Analysis and Countermeasures Center's National Bioforensics Analysis Center will have operational BSL-3 capability in FY2009, it intends to use "spoke" laboratories, such as LLNL's BSL-3, if operational sample numbers exceed it's currently projected capacity.

5. For these reasons, it is my professional opinion that LLNL's BSL-3 facility will significantly improve our Nation's ability to detect and respond to the threat of terrorism using biological agents.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Signed this 26 day of March, 2008.

Susan Elizabeth George

SUSAN ELIZABETH GEORGE